

June 21, 2012

Selina Hallan
Quality Services Manager
Quality Pork Processors, Inc., M1620
711 Hormel Century Parkway
Austin, MN 55912

Dear Ms. Hallan:

This letter is in response to your *Salmonella* Initiative Program (SIP) protocol submission dated November 2, 2011 (Log Number 11-SIP-003-N-A) at Quality Pork Processors, Inc. (Est. M1620); Austin, MN and your waiver requests for the use of alternative:

- procedures for line speed and HACCP-based Inspection Models Project (HIMP) [9 CFR 310.1(b)(3)]; and
- procedures for generic *E. coli* and *Salmonella* sampling and testing [9 CFR 310.25(a) and (b)].

The Food Safety and Inspection Service (FSIS) has completed the review of your requests and is hereby granting your company an approval of the waiver of the regulations pending the Agency amendment of 9 CFR 310.1(b)(3) and 310.25(a) and (b), pursuant under 9 CFR 381.3(b).

FSIS has no objection to Est. M1620 using alternative procedures for line speed in place of 9 CFR 310.1(b)(3), alternative generic *E. coli* sampling and testing in place of 9 CFR 310.25(a), and alternative daily *Salmonella* sampling and testing procedures as described in its SIP Protocol in place of 9 CFR 310.25(b) provided the establishment:

Assesses, modifies and validates as appropriate, the Hazard Analysis and Critical Control Point (HACCP) plan according to 9 CFR 304.3 and 417.4 for:

- the SIP protocol;
- continuing CCPs for Infectious conditions (e.g. pyemia, septicemia, toxemia) (9 CFR 311.16 and 311.17), for Contamination (fecal, ingesta and milk contamination) [(9 CFR 310.18(a)], and for Ante-mortem Suspect (9 CFR 309.2) with zero as the critical limit (CL); and
- continuing the Slaughter Process Control Plan to meet standards of the FSIS "Market Hogs HIMP" Draft dated 06/21/05; and the alternative procedures for line speed [9 CFR 310.1(b)(3)].

Makes available and discuss with FSIS Inspection Program Personnel (IPP) at the weekly meeting or on a conference call with IPP and appropriate District Office the following:

- this SIP Letter which provides that FSIS is granting a waiver of 9 CFR 310.1(b)(3) and 310.25(a) and (b) and has no objection to Est. M1620 using the alternative procedures specified in this letter and the SIP Protocol;
- the alternative procedures the establishment will use as described above;
- the SIP Protocol which identifies the regulations waived, the alternative procedures used, the microbiological sampling and testing implemented and the establishment's agreement to share microbiological sampling and testing results and other data with FSIS; and
- the IPP Verification Overview which:
 - identifies where the establishment has elected to include its alternative procedures and SIP Protocol in its food safety system, and
 - provides specific verification procedures for verifying that the establishment is operating in a manner that is consistent with the alternative procedures and SIP Protocol.
 - **NOTE:** IPP are to verify one or more parts of the alternative procedures or other aspects of the SIP Protocol once per week using an appropriate Public Health Inspection System (PHIS) task and according to instructions in FSIS Directive 5020.1 Verification of SIP.

IPP Verification Overview:

<u>Regulation(s) Waived</u>	<u>Alternative Procedures Verified by IPP</u>	<u>Location in Food Safety System</u>	<u>Regulation(s) to Verify and Cite on NR</u>
310.1(b)(3) (line speed)	HIMP Slaughter Process Control Plan Establishment conducts monitoring according to plan and meets requirements of FSIS – Market Hogs HIMP Draft (06/21/05).	Prerequisite Program	Verify according to FSIS – Market Hogs HIMP Draft (06/21/05) 381.1 and 381.3(b)
310.25(b) (<i>Salmonella</i> Performance Standard)	SIP Protocol : Establishment Microbial Testing A. Frequency	Prerequisite Program	Verify establishment is following SIP Protocol and is therefore supporting decisions

310.25(a) (<i>E. coli</i> testing frequency)	<p>1. Daily: <i>Salmonella</i> postchill samples 1 per line per shift</p> <p>2. Weekly: one matched pair samples per plant for <i>Salmonella</i>, Mesophilic Aerobic Bacteria</p> <p><u>B. Following Sampling and testing procedures</u></p> <p><u>C. Recording and responding to Daily <i>Salmonella</i> test results;</u></p> <p><u>D. If exceed standard:</u></p> <p>1. Increase <i>Salmonella</i> frequency to 2 samples per shift.</p> <p>2. Investigate cause, document corrective actions.</p> <p>3. Return to previous frequency when 2 consecutive sample sets meet standard (no more than 6 positives out of 55 samples).</p> <p>(Generic <i>E. coli</i> frequency is zero).</p>		<p>made in the hazard analysis.</p> <p>417.5(a) & 381.3(b)</p>
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Writes sampling procedures that identify employees designated to collect samples and address locations of sampling, how random sampling will be achieved to cover all lines and all shifts, and how the samples will be handled to ensure sample integrity for *Salmonella*, *E. coli*, and applicable indicator organisms (Mesophilic Aerobic Bacteria).

Conducts microbiological sampling according to the written sampling procedures and at the frequency stated below:

- Every day of production collect one *Salmonella* sample per evisceration line per shift (for a total of 2 samples per day) at the postchill location after all postchill applications the establishment has implemented to reduce microbial contamination of carcasses.
- Each week collect one pre-evisceration sample to compare results to a matched¹ postchill sample for each of the following microbes: *Salmonella*, *E. coli*, and applicable indicator organisms (Mesophilic Aerobic Bacteria).

¹ Pre-evisceration and postchill matched samples—postchill taken after time for carcass to travel from pre-evisceration location, through evisceration and cooler.

NOTE: the alternative daily *Salmonella* testing and weekly pre-evisceration to postchill matched samples are used in place of daily postchill generic *E. coli* testing (9 CFR 310.25(a)).

Records all microbiological test results.

Maintains six² or less positive *Salmonella* test results in a 55 sample set by using discrete sample set to count the number of positives to determine status.

Responds to greater than 6 *Salmonella* positive test results by:

- increasing the frequency of *Salmonella* testing to 4 samples per day;
- reviewing the establishment's total food safety system with consideration given to whether the waiver of requirements has caused the lack of control and take corrective and preventive actions to re-gain control and document those actions; and
- demonstrating restoration of process control by conducting at the increased testing frequency two consecutive sample sets that have 6 or less positive *Salmonella* test results in each 55 sample set. After demonstrating control, the frequency of testing can then return to 1 *Salmonella* sample per line per shift.

NOTE: At this time, it is not necessary to send *Salmonella* isolates to the FSIS Laboratory at Athens, Georgia.

Maintains records in the same manner and for the same duration as HACCP records (9 CFR 417.5).

Allows access to the records necessary to document SIP process control including microbiological test results to FSIS IPP. FSIS requires access to the records at least weekly.

Submits microbiological test results to FSIS headquarters monthly according to the FSIS template and instructions on how to submit (including frequency), which can be obtained by e-mailing the FSIS "SIP.Mailbox@FSIS.USDA.gov."

NOTE: Although FSIS expects that an individual establishment submitting data through the template and following instructions will not be identified, FSIS cannot guarantee that data may not be obtained through the Freedom of Information Act (FOIA).

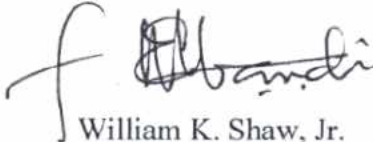
Provides FSIS 30 days prior written notice if the establishment decides to stop participation in the SIP and stop operating under the waivers.

Please be aware that if Quality Pork Processors, Inc. (Est. M1620) system conflicts with the provisions of the Federal Meat Inspection Act (21 U.S.C. 601, et seq.), or has repeated Noncompliance Records (NRs) documenting failure to maintain the alternative procedures or to follow the SIP Protocol, then the waivers will be revoked.

² Note: The expected level of an establishment's performance is contained in this letter or future SIP letters

If you have questions, please contact Isabel Arrington, Risk, Innovations, and Management Division (RIMD), Office of Policy and Program Development (OPPD) at (402) 344-5016 or e-mail Isabel.Arrington@fsis.usda.gov or Selena Kremer, RIMD, OPPD at (301) 504-0855 or email selena.kremer-caldwell@fsis.usda.gov.

Sincerely,



William K. Shaw, Jr.
Director
Risk, Innovations, and Management Division
Office of Policy and Program Development

Attachments:

1. SIP Protocol

cc:

Rachel Edelstein, Acting AA, OPPD
Daniel Engeljohn, AA, OFO
Haroon Mian, EARO, OFO
Phyllis Adams, DM, OFO
Eric Garnighian, DDM, OFO
Andrew Lorenz, DDM, OFO
(b) (6), FLS, OFO
(b) (6), IIC, OFO
Patrick Burke, RIMD, OPPD
Isabel Arrington, RIMD, OPPD
Liza Murray, RIMD, OPPD
Delila Parham, RIMD, OPPD
Nora Pihkala, RIMD, OPPD
Scott Seys, RIMD, OPPD
Selena Kremer, RIMD, OPPD

FSIS:OPPD:RIMD File: Kremer M1620 SIP Letter Number 11-SIP-003-N-A.

June 21, 2012

Kelly Gartner
Compliance Superintendent
Clemens Food Group dba Hatfield Quality Meats, M791
2700 Clemens Road
Hatfield, PA 19440

Dear Ms. Gartner:

This letter is in response to your *Salmonella* Initiative Program (SIP) protocol submission dated November 8, 2011 (Log Number 11-SIP-130-N-A) at Clemens Food Group dba Hatfield Quality Meats (Est. M791); Hatfield, PA and your waiver requests for the use of alternative:

- procedures for line speed and HACCP-based Inspection Models Project (HIMP) [9 CFR 310.1(b)(3)]; and
- procedures for generic *E. coli* and *Salmonella* sampling and testing [9 CFR 310.25(a) and (b)].

The Food Safety and Inspection Service (FSIS) has completed the review of your requests and is hereby granting your company an approval of the waiver of the regulations pending the Agency amendment of 9 CFR 310.1(b)(3) and 310.25(a) and (b), pursuant under 9 CFR 381.3(b).

FSIS has no objection to Est. M791 using alternative procedures for line speed in place of 9 CFR 310.1(b)(3), alternative generic *E. coli* sampling and testing in place of 9 CFR 310.25(a), and alternative daily *Salmonella* sampling and testing procedures as described in its SIP Protocol in place of 9 CFR 310.25(b) provided the establishment:

Assesses, modifies and validates as appropriate, the Hazard Analysis and Critical Control Point (HACCP) plan according to 9 CFR 304.3 and 417.4 for:

- the SIP protocol;
- continuing CCPs for Infectious conditions (e.g. pyemia, septicemia, toxemia) (9 CFR 311.16 and 311.17), for Contamination (fecal, ingesta and milk contamination) [(9 CFR 310.18(a)], and for Ante-mortem Suspect (9 CFR 309.2) with zero as the critical limit (CL); and
- continuing the Slaughter Process Control Plan to meet standards of the FSIS "Market Hogs HIMP" Draft dated 06/21/05; and the alternative procedures for line speed [9 CFR 310.1(b)(3)].

Makes available and discuss with FSIS Inspection Program Personnel (IPP) at the weekly meeting or on a conference call with IPP and appropriate District Office the following:

- this SIP Letter which provides that FSIS is granting a waiver of 9 CFR 310.1(b)(3) and 310.25(a) and (b) and has no objection to Est. M791 using the alternative procedures specified in this letter and the SIP Protocol;
- the alternative procedures the establishment will use as described above;
- the SIP Protocol which identifies the regulations waived, the alternative procedures used, the microbiological sampling and testing implemented and the establishment's agreement to share microbiological sampling and testing results and other data with FSIS; and
- the IPP Verification Overview which:
 - identifies where the establishment has elected to include its alternative procedures and SIP Protocol in its food safety system, and
 - provides specific verification procedures for verifying that the establishment is operating in a manner that is consistent with the alternative procedures and SIP Protocol.
 - **NOTE:** IPP are to verify one or more parts of the alternative procedures or other aspects of the SIP Protocol once per week using an appropriate Public Health Inspection System (PHIS) task and according to instructions in FSIS Directive 5020.1 Verification of SIP.

IPP Verification Overview:

<u>Regulation(s) Waived</u>	<u>Alternative Procedures Verified by IPP</u>	<u>Location in Food Safety System</u>	<u>Regulation(s) to Verify and Cite on NR</u>
310.1(b)(3) (line speed)	HIMP Slaughter Process Control Plan Establishment conducts monitoring according to plan and meets requirements of FSIS – Market Hogs HIMP Draft (06/21/05).	Prerequisite Program	Verify according to FSIS – Market Hogs HIMP Draft (06/21/05) 381.1 and 381.3(b)
310.25(b) (<i>Salmonella</i> Performance Standard)	SIP Protocol : Establishment Microbial Testing A. Frequency	Prerequisite Program	Verify establishment is following SIP Protocol and is therefore supporting decisions

<p>310.25(a) (<i>E. coli</i> testing frequency)</p>	<p>1. Daily: <i>Salmonella</i> postchill samples 1 per line per shift 2. Weekly: one matched pair samples per plant for <i>Salmonella</i>, generic <i>E. coli</i> <u>B. Following Sampling and testing procedures</u> <u>C. Recording and responding to Daily <i>Salmonella</i> test results;</u> <u>D. If exceed standard:</u> 1. Increase <i>Salmonella</i> frequency to 2 samples per shift. 2. Investigate cause, document corrective actions. 3. Return to previous frequency when 2 consecutive sample sets meet standard (no more than 6 positives out of 55 samples).</p> <p>(Generic <i>E. coli</i> frequency is zero).</p>		<p>made in the hazard analysis.</p> <p>417.5(a) & 381.3(b)</p>
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Writes sampling procedures that identify employees designated to collect samples and address locations of sampling, how random sampling will be achieved to cover all lines and all shifts, and how the samples will be handled to ensure sample integrity for *Salmonella* and *E. coli*.

Conducts microbiological sampling according to the written sampling procedures and at the frequency stated below:

- Every day of production collect one *Salmonella* sample per evisceration line per shift (for a total of 1 sample per day) at the postchill location after all postchill applications the establishment has implemented to reduce microbial contamination of carcasses.
- Each week collect one pre-evisceration sample to compare results to a matched¹ postchill sample for each of the following microbes: *Salmonella* and *E. coli*.

¹ Pre-evisceration and postchill matched samples—postchill taken after time for carcass to travel from pre-evisceration location, through evisceration and cooler.

NOTE: the alternative daily *Salmonella* testing and weekly pre-evisceration to postchill matched samples are used in place of daily postchill generic *E. coli* testing (9 CFR 310.25(a)).

Records all microbiological test results.

Maintains six² or less positive *Salmonella* test results in a 55 sample set by using discrete sample set to count the number of positives to determine status.

Responds to greater than 6 *Salmonella* positive test results by:

- increasing the frequency of *Salmonella* testing to 2 samples per day;
- reviewing the establishment's total food safety system with consideration given to whether the waiver of requirements has caused the lack of control and take corrective and preventive actions to re-gain control and document those actions; and
- demonstrating restoration of process control by conducting at the increased testing frequency two consecutive sample sets that have 6 or less positive *Salmonella* test results in each 55 sample set. After demonstrating control, the frequency of testing can then return to 1 *Salmonella* sample per line per shift.

NOTE: At this time, it is not necessary to send *Salmonella* isolates to the FSIS Laboratory at Athens, Georgia.

Maintains records in the same manner and for the same duration as HACCP records (9 CFR 417.5).

Allows access to the records necessary to document SIP process control including microbiological test results to FSIS IPP. FSIS requires access to the records at least weekly.

Submits microbiological test results to FSIS headquarters monthly according to the FSIS template and instructions on how to submit (including frequency), which can be obtained by e-mailing the FSIS "SIP.Mailbox@FSIS.USDA.gov."

NOTE: Although FSIS expects that an individual establishment submitting data through the template and following instructions will not be identified, FSIS cannot guarantee that data may not be obtained through the Freedom of Information Act (FOIA).

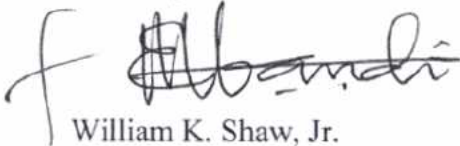
Provides FSIS 30 days prior written notice if the establishment decides to stop participation in the SIP and stop operating under the waivers.

Please be aware that if Clemens Food Group dba Hatfield Quality Meats (Est. M791) system conflicts with the provisions of the Federal Meat Inspection Act (21 U.S.C. 601, et seq.), or has repeated Noncompliance Records (NRs) documenting failure to maintain the alternative procedures or to follow the SIP Protocol, then the waivers will be revoked.

² Note: The expected level of an establishment's performance is contained in this letter or future SIP letters

If you have questions, please contact Isabel Arrington, Risk, Innovations, and Management Division (RIMD), Office of Policy and Program Development (OPPD) at (402) 344-5016 or e-mail Isabel.Arrington@fsis.usda.gov or Selena Kremer, RIMD, OPPD at (301) 504-0855 or email selena.kremer-caldwell@fsis.usda.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Shaw, Jr.", with a large, stylized initial "W" and "S".

William K. Shaw, Jr.

Director

Risk, Innovations, and Management Division
Office of Policy and Program Development

Attachments:

1. SIP Protocol

cc:

Rachel Edelstein, Acting AA, OPPD

Daniel Engeljohn, AA, OFO

Armia Tawadrous, EARO, OFO

Jan Behney, DM, OFO

Paul Brinig, DDM, OFO

Susan Scarcia, DDM, OFO

(b) (6), FLS, OFO

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Patrick Burke, RIMD, OPPD

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Liza Murray, RIMD, OPPD

Delila Parham, RIMD, OPPD

Nora Pihkala, RIMD, OPPD

Scott Seys, RIMD, OPPD

Selena Kremer, RIMD, OPPD

FSIS:OPPD:RIMD File: Kremer M791 SIP Letter Number 11-SIP-130-N-A.

September 27, 2012

Mr. Steve Wedeking
Technical Services Manager
Cargill Meat Solutions, M85 B
8295 Arenzville Road
Beardstown, IL 62618

Dear Mr. Wedeking:

This letter is in response to your revised *Salmonella* Initiative Program (SIP) protocol submission dated August 21, 2012, (Log Number 11-SIP-131-N-A) at Cargill Meat Solutions (Est. M85 B); Beardstown, IL and your waiver requests for the use of alternative:

- procedures for line speed and HACCP-based Inspection Models Project (HIMP) [9 CFR 310.1(b)(3)]; and
- procedures for generic *E. coli* and *Salmonella* sampling and testing [9 CFR 310.25(a) and (b)].

The Food Safety and Inspection Service (FSIS) has completed the review of your requests and is hereby granting your company an approval of the waiver of the regulations pending the Agency amendment of 9 CFR 310.1(b)(3) and 310.25(a) and (b), pursuant under 9 CFR 303.1(h).

FSIS has no objection to Est. M85 B using alternative procedures for line speed in place of 9 CFR 310.1(b)(3), alternative generic *E. coli* sampling and testing in place of 9 CFR 310.25(a), and alternative daily *Salmonella* sampling and testing procedures as described in its SIP Protocol in place of 9 CFR 310.25(b) provided the establishment:

Assesses, modifies and validates as appropriate, the Hazard Analysis and Critical Control Point (HACCP) plan according to 9 CFR 304.3 and 417.4 for:

- the SIP protocol;
- continuing CCPs for Infectious conditions (e.g. pyemia, septicemia, toxemia) (9 CFR 311.16 and 311.17), for Contamination (fecal, ingesta and milk contamination) [(9 CFR 310.11 and 310.18(a)], and for Ante-mortem Suspect (9 CFR 309.2) with zero as the critical limit (CL); and
- continuing the Slaughter Process Control Plan to meet standards of the FSIS "Market Hogs HIMP" Draft dated 06/21/05; and the alternative procedures for line speed [9 CFR 310.1(b)(3)].

Makes available and discuss with FSIS Inspection Program Personnel (IPP) at the weekly meeting or on a conference call with IPP and appropriate District Office the following:

- this SIP Letter which provides that FSIS is granting a waiver of 9 CFR 310.1(b)(3) and 310.25(a) and (b) and has no objection to Est. M85 B using the alternative procedures specified in this letter and the SIP Protocol;
- the alternative procedures the establishment will use as described above;
- the SIP Protocol which identifies the regulations waived, the alternative procedures used, the microbiological sampling and testing implemented and the establishment's agreement to share microbiological sampling and testing results and other data with FSIS; and
- the IPP Verification Overview which:
 - identifies where the establishment has elected to include its alternative procedures and SIP Protocol in its food safety system, and
 - provides specific verification procedures for verifying that the establishment is operating in a manner that is consistent with the alternative procedures and SIP Protocol.
 - **NOTE:** IPP are to verify one or more parts of the alternative procedures or other aspects of the SIP Protocol once per week using an appropriate Public Health Inspection System (PHIS) task and according to instructions in FSIS Directive 5020.1 Verification of SIP.

IPP Verification Overview:

<u>Regulation(s) Waived</u>	<u>Alternative Procedures Verified by IPP</u>	<u>Location in Food Safety System</u>	<u>Regulation(s) to Verify and Cite on NR</u>
310.1(b)(3) (line speed)	HIMP Slaughter Process Control Plan Establishment conducts monitoring according to plan and meets requirements of FSIS – Market Hogs HIMP Draft (06/21/05).	Prerequisite Program	Verify according to FSIS – Market Hogs HIMP Draft (06/21/05) 303.1(h)
310.25(b) (<i>Salmonella</i> Performance Standard)	SIP Protocol : Establishment Microbial Testing A. Frequency 1. Daily: <i>Salmonella</i>	Prerequisite Program	Verify establishment is following SIP Protocol and is therefore supporting decisions made in the hazard

	postchill samples 1 per line per shift 2. Weekly : one matched pair samples per plant for <i>Salmonella</i> , generic <i>E. coli</i> <u>B. Following Sampling and testing procedures</u> <u>C. Recording and responding to Daily <i>Salmonella</i> test results;</u> <u>D. If exceed standard:</u> 1. Increase <i>Salmonella</i> frequency to 2 samples per shift. 2. Investigate cause, document corrective actions. 3. Return to previous frequency when 2 consecutive sample sets meet standard (no more than 6 positives out of 55 samples).		analysis. 303.1(h)
310.25(a) (<i>E. coli</i> testing frequency)	Generic <i>E. coli</i> frequency per regulatory requirements.	Regulatory Requirement	Verify establishment is following 310.25 (a) testing frequency per 310.25(a) & 303.1(h).

Writes sampling procedures that identify employees designated to collect samples and address locations of sampling, how random sampling will be achieved to cover all lines and all shifts, and how the samples will be handled to ensure sample integrity for *Salmonella* and generic *E. coli*.

Conducts microbiological sampling according to the written sampling procedures and at the frequency stated below:

- Every day of production collect one *Salmonella* sample per evisceration line per shift (for a total of 2 samples per day) at the postchill location after all postchill applications the establishment has implemented to reduce microbial contamination of carcasses.
- Each week collect one pre-evisceration sample to compare results to a matched¹ postchill sample for each of the following microbes: *Salmonella* and generic *E. coli*.

¹ Pre-evisceration and postchill matched samples—postchill taken after time for carcass to travel from pre-evisceration location, through evisceration and cooler.

Records all microbiological test results.

Maintains six² or less positive *Salmonella* test results in a 55 sample set by using a moving window to count the number of positives to determine status.

Responds to greater than 6 *Salmonella* positive test results by:

- increasing the frequency of *Salmonella* testing to 4 samples per day;
- reviewing the establishment's total food safety system with consideration given to whether the waiver of requirements has caused the lack of control and take corrective and preventive actions to re-gain control and document those actions; and
- demonstrating restoration of process control by conducting at the increased testing frequency two consecutive sample sets that have 6 or less positive *Salmonella* test results in each 55 sample set. After demonstrating control, the frequency of testing can then return to 1 *Salmonella* sample per line per shift.

NOTE: At this time, it is not necessary to send *Salmonella* isolates to the FSIS Laboratory at Athens, Georgia.

Maintains records in the same manner and for the same duration as HACCP records (9 CFR 417.5).

Allows access to the records necessary to document SIP process control including microbiological test results to FSIS IPP. FSIS requires access to the records at least weekly.

Submits microbiological test results to FSIS headquarters monthly according to the FSIS template and instructions on how to submit (including frequency), which can be obtained by e-mailing the FSIS "SIP.Mailbox@FSIS.USDA.gov."

NOTE: Although FSIS expects that an individual establishment submitting data through the template and following instructions will not be identified, FSIS cannot guarantee that data may not be obtained through the Freedom of Information Act (FOIA).

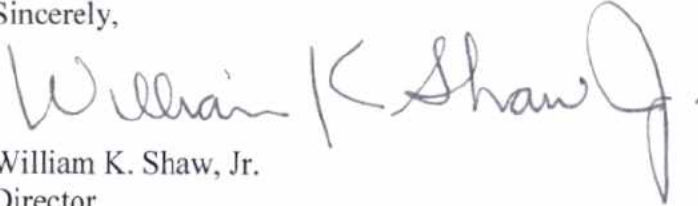
Provides FSIS 30 days prior written notice if the establishment decides to stop participation in the SIP and stop operating under the waivers.

Please be aware that if Cargill Meat Solutions (Est. M85 B) system conflicts with the provisions of the Federal Meat Inspection Act (21 U.S.C. 601, et seq.), or has repeated Noncompliance Records (NRs) documenting failure to maintain the alternative procedures or to follow the SIP Protocol, then the waivers will be revoked.

² Note: The expected level of an establishment's performance is contained in this letter or future SIP letters

If you have questions, please contact Isabel Arrington, Risk, Innovations, and Management Division (RIMD), Office of Policy and Program Development (OPPD) at (402) 344-5016 or e-mail Isabel.Arrington@fsis.usda.gov or Selena Kremer, RIMD, OPPD at (301) 504-0855 or email selena.kremer-caldwell@fsis.usda.gov.

Sincerely,

A handwritten signature in black ink that reads "William K. Shaw, Jr." The signature is written in a cursive, flowing style.

William K. Shaw, Jr.

Director

Risk, Innovations, and Management Division
Office of Policy and Program Development

Attachments:

1. SIP Protocol

cc:

Rachel Edelstein, Acting AA, OPPD

Daniel Engeljohn, AA, OFO

Hany Sidrak, EARO, OFO

Paul Wolseley, DM, OFO

Tamara Mayberry, DDM, OFO

(b) (6), FLS, OFO

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Patrick Burke, RIMD, OPPD

Isabel Arrington, RIMD, OPPD

Liza Murray, RIMD, OPPD

Delila Parham, RIMD, OPPD

Nora Pihkala, RIMD, OPPD

Scott Seys, RIMD, OPPD

Selena Kremer, RIMD, OPPD

FSIS:OPPD:RIMD File: Kremer M85 B SIP Letter Number 11-SIP-131-N-A.

September 2, 2014

Joel Coble
Senior Director Food Safety & Quality Assurance
Food Safety and Regulatory Compliance Manager
Tyson Fresh Meats, Inc., M00244L
800 Stevens Port Drive
Dakota Dunes, SD 57049

Dear Mr. Coble:

This letter is in response to your *Salmonella* Initiative Program (SIP) protocol submission dated June 5, 2014, (Log Number 14-SIP-0159-N-A) at Tyson Fresh Meats, Inc. (Est. M244L); Columbus Junction, IA and your waiver requests for the use of alternative procedures:

- to remove certain dressing defects (9 CFR 310.11); and
- for generic *E. coli* and *Salmonella* sampling and testing [9 CFR 310.25(a) and (b)].

The Food Safety and Inspection Service (FSIS) has completed the review of your requests and is hereby granting your company a waiver of the regulations pending the Agency amendment of 9 CFR 310.11 and 310.25(a) and (b), pursuant under 9 CFR 303.1(h).

FSIS has no objection to Est. M244L using alternative procedures to remove certain dressing defects in place of 9 CFR 310.11; alternative generic *E. coli* testing in place of 9 CFR 310.25(a); and, as described in its SIP Protocol, using alternative daily *Salmonella* sampling and testing procedures in place of 9 CFR 310.25(b) provided the establishment:

1. Assesses, modifies and validates as appropriate, the Hazard Analysis and Critical Control Point (HACCP) plan according to 9 CFR 304.3 and 417.4 for:
 - the SIP protocol;
 - alternative procedures for removing eyelids and eyelash stubble remaining on carcasses after the dehairing process (and after the first incision) by a hole-punch device that marks the eye and eyelid to ensure that the eyelids on the skull, with any hair present, are removed when the snout is pulled from the head provided the Pork Slaughter Sanitary Dressing Best Practices and Statistical Process Control (SPC) In Process Audit Procedure continually demonstrate process control including taking corrective action if control limits are exceeded in place of 9 CFR 310.11;
 - alternative procedures for removing incidental carcass hair that is not readily visible (does not require frisking or rubbing the hog to visualize) or exists visually under the dermis layers at locations after the first incision provided the Pork Slaughter Sanitary

Dressing Best Practices and SPC In Process Audit Procedure continually demonstrate process control, including taking corrective action if control limits are exceeded, in place of 9 CFR 310.11; and

2. Ensures that the post-evisceration, pre-final rail carcass wash is turned off if carcasses with visible, incidental fecal or oral ingesta or certain pathological conditions are found before the wash.
3. Validates in-plant within 90 days of implementing the alternative procedures for removal of eyelids and eyelash stubble and for removal of not readily visible incidental hairs.
4. Makes available and discuss with FSIS Inspection Program Personnel (IPP) at the weekly meeting or on a conference call with IPP and appropriate District Office the following:
 - this SIP Letter which provides that FSIS is granting a waiver of 9 CFR 310.11 and 310.25(a) and (b), and has no objection to Est. M244L using the alternative procedures specified in this letter and the SIP Protocol;
 - the alternative procedures the establishment will use as described above;
 - the SIP Protocol which identifies the regulations waived, the alternative procedures used, the microbiological sampling and testing implemented and the establishment's agreement to share microbiological sampling and testing results and other data with FSIS; and
 - the IPP Verification Overview which:
 - identifies where the establishment has elected to include its alternative procedures and SIP Protocol in its food safety system, and
 - provides specific verification procedures for verifying that the establishment is operating in a manner that is consistent with the alternative procedures and SIP Protocol.

NOTE: IPP are to verify one or more parts of the alternative procedures or other aspects of the SIP Protocol once per week using an appropriate Public Health Inspection System (PHIS) task and according to instructions in FSIS Directive 5020.1 Verification of SIP.

IPP Verification Overview:

<u>Regulation(s) Waived</u>	<u>Alternative Procedures Verified by IPP</u>	<u>Location in Food Safety System</u>	<u>Regulation(s) to Verify and Cite on NR</u>
9 CFR 310.11 (Hair Removal)	Using the alternative procedures for removing eyelids and eyelash stubble remaining on carcasses after the	Prerequisite Program	Verify establishment is following alternative procedures 9 CFR 310.11 & 303.1(h)

	dehairing process (and after the first incision) by a hole-punch device that marks the eye and eyelid to ensure that the eyelids on the skull, with any hair present, are removed when the snout is pulled from the head provided the Pork Slaughter Sanitary Dressing Best Practices and SPC In Process Audit Procedure continually demonstrate process control including investigating and taking corrective actions if control limits are exceeded.		
9 CFR 310.11 (Hair removal)	Using the alternative procedures for removing incidental carcass hair that is not readily visible (does not require frisking or rubbing the hog to visualize) or exists visually under the dermis layers at a location after the first incision provided the Pork Slaughter Sanitary Dressing Best Practices and SPC In Process Audit Procedure continually demonstrate process control including investigating and taking corrective actions if control limits are exceeded.	Prerequisite Program	Verify establishment is following alternative procedures 9 CFR 310.11 & 303.1(h)
310.25(b) (<i>Salmonella</i> Performance Standard)	SIP Protocol : Establishment Microbial Testing A. <u>Frequency</u>	Prerequisite Program	Verify establishment is following SIP Protocol and is therefore supporting decisions made in the hazard

	<p>1. Daily: <i>Salmonella</i> postchill samples 1 per line per shift</p> <p>2. Weekly: one matched pair samples per day for <i>Salmonella</i>, <i>Enterobacteriaceae</i> (EB)</p> <p><u>B. Following Sampling and testing procedures</u></p> <p><u>C. Recording and responding to Daily <i>Salmonella</i> test results;</u></p> <p><u>D. If exceed standard:</u></p> <p>1. Increase <i>Salmonella</i> frequency to 2 samples per shift.</p> <p>2. Investigate cause, document corrective actions.</p> <p>3. Return to previous frequency when 2 consecutive sample sets meet standard (no more than 6 positives out of 55 samples).</p>		<p>analysis.</p> <p>417.5(a) & 303.1(h)</p>
310.25(a) (<i>E. coli</i> testing frequency)	Generic <i>E. coli</i> frequency is zero.	Alternative frequency is zero.	

5. Writes sampling procedures that identify employees designated to collect samples and address locations of sampling, how random sampling will be achieved to cover all lines and all shifts, and how the samples will be handled to ensure sample integrity for *Salmonella* and applicable indicator organisms [*Enterobacteriaceae* (EB)].
6. Conducts microbiological sampling according to the written sampling procedures and at the frequency stated below:
 - Every day of production collect one *Salmonella* sample per evisceration line per shift (for a total of 1 sample per day) at the postchill location after all postchill applications the establishment has implemented to reduce microbial contamination of carcasses.

- Each week collect one pre-evisceration sample to compare results to a matched¹ postchill sample for each of the following microbes: *Salmonella* and *EB*.

NOTE: the alternative daily *Salmonella* testing and weekly *Salmonella* and *EB* pre-evisceration to postchill matched samples are used in place of daily postchill generic *E. coli* testing [9 CFR 310.25(a)].

7. Records all microbiological test results.
8. Maintains six² or less positive *Salmonella* test results in a 55 sample set by using discrete sample set to count the number of positives to determine status.
9. Responds to greater than 6 *Salmonella* positive test results by:
 - increasing the frequency of *Salmonella* testing to 2 samples per day;
 - reviewing the establishment's total food safety system with consideration given to whether the waiver of requirements has caused the lack of control and take corrective and preventive actions to re-gain control and document those actions; and
 - demonstrating restoration of process control by conducting at the increased testing frequency two consecutive sample sets that have 6 or less positive *Salmonella* test results in each 55 sample set. After demonstrating control, the frequency of testing can then return to 1 *Salmonella* sample per line per shift.

NOTE: At this time, it is not necessary to send *Salmonella* isolates to the FSIS Laboratory at Athens, Georgia.

10. Maintains records in the same manner and for the same duration as HACCP records (9 CFR 417.5).
11. Allows access to the records necessary to document SIP process control including microbiological test results to FSIS IPP. FSIS requires access to the records at least weekly.
12. Submits microbiological test results to FSIS headquarters monthly according to the FSIS template and instructions on how to submit (including frequency), which can be obtained by e-mailing the FSIS "SIP.Mailbox@FSIS.USDA.gov."

NOTE: Although FSIS expects that an individual establishment submitting data through the template and following instructions will not be identified, FSIS cannot guarantee that data may not be obtained through the Freedom of Information Act (FOIA).

¹ Pre-evisceration and postchill matched samples—postchill taken after time for carcass to travel from pre-evisceration location, through evisceration and cooler.

² Note: The expected level of an establishment's performance is contained in this letter or future SIP letters

13. Provides FSIS 30 days prior written notice if the establishment decides to stop participation in the SIP and stop operating under the waivers.

Please be aware that if Tyson Fresh Meats, Inc. (Est. M244L) system conflicts with the provisions of the Federal Meat Inspection Act (21 U.S.C. 601, et seq.), or has repeated Noncompliance Records (NRs) documenting failure to maintain the alternative procedures or to follow the SIP Protocol, then the waivers will be revoked.

If you have questions, please contact Isabel Arrington, Risk, Innovations, and Management Division (RIMS), Office of Policy and Program Development (OPPD) at (402) 344-5016 or e-mail Isabel.Arrington@fsis.usda.gov or Scott Seys, RIMS, OPPD at (612) 659-7053 or email scott.seys@fsis.usda.gov.

Sincerely,

F 

William K. Shaw, Jr.

Director

Risk, Innovations, and Management Division
Office of Policy and Program Development

Attachments:

1. SIP Protocol
2. In Process Control Audit

cc:

Daniel Engeljohn, AA, OPPD
William Smith, AA, OFO
Hany Sidrak, EARO, OFO
Dawn Sprouls, DM, OFO
Todd Gerwig, DDM, OFO
Rosemary Turner, DDM, OFO
Khalid Masood, DDM, OFO
(b) (6) FLS, OFO
(b) (6) IC, OFO
Isabel Arrington, RIMS, OPPD
Liza Murray, RIMS, OPPD
Nora Pihkala, RIMS, OPPD
Scott Seys, RIMS, OPPD
Selena Kremer, RIMS, OPPD

FSIS:OPPD:RIMS File: M244L SIP Letter Number 14-SIP-0159-N-A.



Food Safety and
Inspection Service

July 8, 2016

1400 Independence
Avenue, SW,
Washington, D.C.
20250

Joel Coble
Senior Director Food Safety & Quality Assurance
Food Safety and Regulatory Compliance Manager
Tyson Fresh Meats, Inc.,
800 Stevens Port Drive
Dakota Dunes, SD 57049

Dear Mr. Coble:

This letter is in response to your *Salmonella* Initiative Program (SIP) protocol submission dated December 16, 2014 (and assigned Log Number 14-SIP-0162-N-A) at Tyson Fresh Meats, Inc. (Est. M244I); Logansport, IN. You have submitted a cover letter and SIP protocol requesting the Food Safety and Inspection Service (FSIS) to grant waivers of 9 CFR 310.11, 310.25 (a) and (b) and in place of the waived regulations use alternative procedures:

1. to remove certain dressing defects (9 CFR 310.11); and
2. for generic *E. coli* and *Salmonella* sampling and testing [9 CFR 310.25(a) and (b)].

The protocol submitted includes a pre-requisite program (Pork Carcass Prep™) that uses best practices to address and minimize visible hair and other dressing or contamination defects at all components/sections of slaughter dressing. In conjunction with the best practices a process control procedure, In-Process Contamination Audit (IPCA) using lot acceptance techniques with mandatory control limits and assigning controls in the process to target in process contamination prevention and minimization at the 5 steps in the slaughter process.

Background:

The SIP is a voluntary program for meat and poultry slaughter establishments that agree to test for *Salmonella*, *Campylobacter* (if applicable) and indicator organisms and share all sample results and other corresponding process control data with FSIS in order to receive waivers of provisions of the regulations (76 FR 41186, July 13, 2011). Establishments participating in SIP maintain consistent process control for *Salmonella* and use contamination process control verification

activities to determine control limits along with *Salmonella* and indicator organism test results.

The protocol submitted includes Pork PREP (Sanitary dressing best practices and an In Process Audit procedure pre-requisite program) to gauge process capability and performance of carcass dressing procedures in relation to carcass cleanliness consistently monitor changes and control of slaughter hygiene. This In Process Contamination (IPC) audit (Attachment 1) serves as a process control procedure that targets in-process contamination prevention and minimization rather than removal. The audit program is to implement in conjunction with the pork slaughter sanitary dressing best practices pre-requisite program (Carcass PREP Attachment 1) which addresses all components/sections of the slaughter dressing operations.

Establishments participating in SIP are to maintain consistent process control for *Salmonella* and use sanitary dressing procedures for preventing visible contamination (or ingesta, feces and milk contamination) and include verification activities in addition to determining control limits for *Salmonella* and indicator organism test results.

Waivers granted and Establishment Agreement:

The Food Safety and Inspection Service (FSIS) has completed the review of your requests and is hereby granting your establishment a waiver of the regulations pending the Agency amendment of 9 CFR 310.11 and 310.25(a) and (b), pursuant to provisions under 9 CFR 303.1(h).

FSIS has no objection to Est. M244I using alternative procedures to remove certain dressing defects in place of 9 CFR 310.11; alternative generic *E. coli* testing in place of 9 CFR 310.25(a); and, as described in its SIP Protocol, using alternative daily *Salmonella* sampling and testing procedures in place of 9 CFR 310.25(b) provided the establishment:

A. Reassesses, modifies and validates as appropriate, the Hazard Analysis and Critical Control Point (HACCP) food safety system (HACCP plan, Sanitation-SOP or other prerequisite program) according to 9 CFR 304.3, 416 and 417.4 for:

1. the SIP protocol;
2. alternative procedures used in place of 9 CFR 310.11 for removing eyelids and eyelash stubble remaining on carcasses after dehairing and first incision by a hole-punch device to ensure that the eyelids on the skull, with any hair present, are removed when the snout is pulled from the head provided; the Pork Carcass PREP best practices (Attachment 1) and the In-Process Contamination (IPC) audit program (Attachment 1) continually demonstrate

process control, as per protocols including taking corrective action if control limits are exceeded;

3. alternative procedures used in place of 9 CFR 310.11 for removing incidental carcass hair that is not readily visible (does not require frisking or rubbing the hog to visualize) or exists visually under the dermis layers at locations after first incision provided the Pork Carcass PREP best practices (Attachment 1) and IPC (Attachment 2) continually demonstrate process control, including taking corrective action if control limits are exceeded; and

B. Ensures that the post-evisceration, pre-final rail carcass wash at audit step 5 is turned off if carcasses with visible, incidental fecal or oral ingesta or certain pathological conditions are found before the wash (at audit 5 step).

C. Validates in-plant within 90 days of implementing the alternative procedures for removal of eyelids and eyelash stubble and for removal of not readily visible incidental hairs.

D. Makes available and discusses with FSIS Inspection Program Personnel (IPP) at the weekly meeting this SIP Letter and SIP Protocol including:

1. regulations waived (9 CFR 310.11, 310.25(a) and (b)),
2. alternative procedures the establishment will use in place of each waived regulation,
3. specified microbiological sampling and testing implemented including records,
4. the establishment's agreement to share microbiological sampling and testing results with FSIS and
5. Attachment 2: FSIS SIP Summary and IPP Verification which summarizes IPP verification procedures for verifying that the establishment is operating in a manner that is consistent with the alternative procedures and SIP Protocol.

E. Conducts microbiological sampling agreed to as condition of receiving the waiver under SIP as follows:

1. Write sampling collection procedures that identify employees 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* and *Enterobacteriaceae* (EB).

2. Conduct microbiological sampling according to the written sampling procedures and at the frequency stated below:
 - a. Every day of production collect one *Salmonella* sample per line per shift at the postchill location after any postchill antimicrobial intervention applications the establishment has implemented to reduce microbial contamination of carcasses.
 - b. Each week collect one pre-evisceration sample to compare results to a matched¹ postchill sample for each of the following microbes: *Salmonella* and EB.
3. Record all microbiological test results.
4. Maintain *Salmonella* process control (currently six² or less positive *Salmonella* test results in a 55 sample set size).
5. Evaluate daily *Salmonella* test results by counting the number of positives in a moving window of 51 samples.
6. Respond to greater than six *Salmonella* positive test results in a 55 sample set by:
 - a. Increasing the frequency of *Salmonella* testing to two samples per line per shift (for a total of four samples per day) until 2 consecutive discrete sample sets have six or less positive *Salmonella* test results in each sample set.
 - b. Reviewing the establishment's total food safety system with consideration given to whether the waiver of requirements has caused the lack of control.
 - c. Taking corrective and preventive actions to re-gain control and documenting findings and resulting actions.

¹ Pre evisceration and postchill matched samples—postchill taken after carcass is chilled in cooler

² Note: The expected level of an establishment's performance is subject to change if the performance standard changes.

d. Demonstrating restoration of control following any corrective action by conducting at the increased frequency of testing, 2 consecutive *Salmonella* sample sets of 55 with six or less positive test results per sample set. After demonstrating control, the frequency of testing can then return to 1 *Salmonella* sample per line per shift

NOTE: At this time, it is not necessary to send *Salmonella* isolates to the FSIS Laboratory at Athens, Georgia.

- F. Maintain records in same manner and for the same duration as HACCP records (9 CFR 417.5).
- G. Provide access to the records necessary to document SIP process control, including microbiological test results when requested by FSIS IPP.
- H. Submit microbiological test results to FSIS headquarters monthly according to the FSIS template and instructions on how to submit which can be obtained by e-mailing the FSIS "SIP.Mailbox@FSIS.USDA.gov".

NOTE: Although FSIS expects that an individual establishment submitting data through the template and following instructions will not be identified, FSIS cannot guarantee that data may not be obtained through the Freedom of Information Act (FOIA).

- I. Provides FSIS 30 days prior written notice if the establishment decides to stop participation in the SIP and stop functioning under the waivers.

IPP Verification Responsibilities:

- A. FSIS Attachment 2. FSIS SIP Summary and IPP Verification provides specific verification procedures that IPP are to use to verify that the establishment is operating in a manner that is consistent with the alternative procedures and SIP Protocol.
- B. IPP are to conduct verification tasks based on how the establishment has incorporated alternative procedures into its food safety system (HACCP plan, Sanitation-SOP or other pre-requisite program) and in accordance with FSIS Directive 5000.1 Verifying an Establishment's Food Safety System.

- C. Once a week IPP are to verify one or more parts of the alternative procedures, SIP sampling and testing and SIP Protocol according to instructions in FSIS Directive 5020.1 Verification of SIP. If the SIP protocol disagrees with the SIP Letter, verify according to the SIP Letter requirements and issue non-compliance records (NRs) as appropriate.
- D. IPP are to verify that the establishment is conducting and implementing the required SIP microbiological sampling and testing according to this SIP letter and SIP Protocol. IPP are to verify that the establishment is;
1. Conducting microbiological sampling according to written procedures;
 2. Recording and evaluating the test results;
 3. Responding when the allowable number of positives is exceeded by increasing testing frequency until two consecutive sample sets have 5 or less positive *Salmonella* results; and
 4. Investigating the cause and document any corrective actions.
- E. IPP are not to write a noncompliance report (NR) if allowable number of *salmonella* positives is exceeded. IPP are to write NRs when the establishment does not follow alternative procedures authorized by the waiver, doesn't maintain records that reflect its use of those procedure or doesn't follow sampling and testing written procedures required under SIP. When noncompliance is found IPP are to take appropriate action and follow instructions in FSIS Directive 5000.1, Ch. V. Documentation and Enforcement. IPP are to report through their supervisor channels if he or she observes a trend of repeated NRs related to the alternative procedures or SIP protocol.

Please be aware that if Tyson Fresh Meats, Inc. (Est. M244I) system conflicts with the provisions of the Federal Meat Inspection Act (21 U.S.C. 601, et seq.), or has repeated Noncompliance Records (NRs) documenting failure to maintain the alternative procedures or to follow the SIP Protocol, then the waivers will be revoked.

If you have questions, please contact, Melanie Abley Risk, Innovations, and Management Staff (RIMS), Office of Policy and Program Development (OPPD) at (202) 690-5673 or e-mail Melanie.Abley@fsis.usda.gov or Scott Seys, RIMS, OPPD at (612) 659-7053 or email scott.seys@fsis.usda.gov.

Sincerely,

F 

William K. Shaw, Jr.

Director

Risk, Innovations, and Management Staff
Office of Policy and Program Development

Attachments:

1. SIP Protocol and Attachment 1, 2, 3, 4
2. FSIS SIP Summary and IPP Verification

cc:

Daniel Engeljohn, AA, OPPD

William Smith, AA, OFO

Hany Sidrak, EARO, OFO

Paul Wolsey DM

Tamara Mayberry, DDM

Mudahar Karnail, DDM

Naquib Mounira, DDM

(b) (6) FLS

(b) (6) SPHV/IIC

(b) (6) PHV,

Melanie Abley RIMS, OPPD

Liza Murray, RIMS, OPPD

Scott Seys, RIMS, OPPD

Isabel Arrington, PDS, OPPD

August 8, 2012

Mr. Brent Hood
QC Manager
Hormel Foods, M199 N
900 South Platt Avenue
Fremont, NE 68025

Dear Mr. Hood:

This letter is in response to your *Salmonella* Initiative Program (SIP) protocol submission dated November 8, 2011 (Log Number 11-SIP-128-N-A) at Hormel Foods (Est. M199 N); Fremont, NE and your waiver requests for the use of alternative:

- procedures for line speed and HACCP-based Inspection Models Project (HIMP) [9 CFR 310.1(b)(3)]; and
- procedures for generic *E. coli* and *Salmonella* sampling and testing [9 CFR 310.25(a) and (b)].

The Food Safety and Inspection Service (FSIS) has completed the review of your requests and is hereby granting your company an approval of the waiver of the regulations pending the Agency amendment of 9 CFR 310.1(b)(3) and 310.25(a) and (b), pursuant under 9 CFR 303.1(h).

FSIS has no objection to Est. M199 N using alternative procedures for line speed in place of 9 CFR 310.1(b)(3), alternative generic *E. coli* sampling and testing in place of 9 CFR 310.25(a), and alternative daily *Salmonella* sampling and testing procedures as described in its SIP Protocol in place of 9 CFR 310.25(b) provided the establishment:

Assesses, modifies and validates as appropriate, the Hazard Analysis and Critical Control Point (HACCP) plan according to 9 CFR 304.3 and 417.4 for:

- the SIP protocol;
- continuing CCPs for Infectious conditions (e.g. pyemia, septicemia, toxemia) (9 CFR 311.16 and 311.17), for Contamination (fecal, ingesta and milk contamination) [(9 CFR 310.18(a)], and for Ante-mortem Suspect (9 CFR 309.2) with zero as the critical limit (CL); and
- continuing the Slaughter Process Control Plan to meet standards of the FSIS "Market Hogs HIMP" Draft dated 06/21/05; and the alternative procedures for line speed [9 CFR 310.1(b)(3)].

Makes available and discuss with FSIS Inspection Program Personnel (IPP) at the weekly meeting or on a conference call with IPP and appropriate District Office the following:

- this SIP Letter which provides that FSIS is granting a waiver of 9 CFR 310.1(b)(3) and 310.25(a) and (b) and has no objection to Est. M199 N using the alternative procedures specified in this letter and the SIP Protocol;
- the alternative procedures the establishment will use as described above;
- the SIP Protocol which identifies the regulations waived, the alternative procedures used, the microbiological sampling and testing implemented and the establishment's agreement to share microbiological sampling and testing results and other data with FSIS; and
- the IPP Verification Overview which:
 - identifies where the establishment has elected to include its alternative procedures and SIP Protocol in its food safety system, and
 - provides specific verification procedures for verifying that the establishment is operating in a manner that is consistent with the alternative procedures and SIP Protocol.
 - **NOTE:** IPP are to verify one or more parts of the alternative procedures or other aspects of the SIP Protocol once per week using an appropriate Public Health Inspection System (PHIS) task and according to instructions in FSIS Directive 5020.1 Verification of SIP.

IPP Verification Overview:

<u>Regulation(s) Waived</u>	<u>Alternative Procedures Verified by IPP</u>	<u>Location in Food Safety System</u>	<u>Regulation(s) to Verify and Cite on NR</u>
310.1(b)(3) (line speed)	HIMP Slaughter Process Control Plan Establishment conducts monitoring according to plan and meets requirements of FSIS – Market Hogs HIMP Draft (06/21/05).	Prerequisite Program	Verify according to FSIS – Market Hogs HIMP Draft (06/21/05) 303.1(h)
310.25(b) (<i>Salmonella</i> Performance Standard)	SIP Protocol : Establishment Microbial Testing A. Frequency	Prerequisite Program	Verify establishment is following SIP Protocol and is therefore supporting decisions

310.25(a) (<i>E. coli</i> testing frequency)	<p>1. Daily: <i>Salmonella</i> postchill samples 1 per line per shift</p> <p>2. Weekly: one matched pair samples per plant for <i>Salmonella</i>, Mesophilic Aerobic Bacteria</p> <p><u>B. Following Sampling and testing procedures</u></p> <p><u>C. Recording and responding</u> to Daily <i>Salmonella</i> test results;</p> <p><u>D. If exceed standard:</u></p> <p>1. Increase <i>Salmonella</i> frequency to 2 samples per shift.</p> <p>2. Investigate cause, document corrective actions.</p> <p>3. Return to previous frequency when 2 consecutive sample sets meet standard (no more than 6 positives out of 55 samples).</p> <p>(Generic <i>E. coli</i> frequency is zero).</p>		<p>made in the hazard analysis.</p> <p>303.1(h)</p>
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Writes sampling procedures that identify employees designated to collect samples and address locations of sampling, how random sampling will be achieved to cover all lines and all shifts, and how the samples will be handled to ensure sample integrity for *Salmonella* and applicable indicator organisms (Mesophilic Aerobic Bacteria).

Conducts microbiological sampling according to the written sampling procedures and at the frequency stated below:

- Every day of production collect one *Salmonella* sample per evisceration line per shift (for a total of 1 sample per day) at the postchill location after all postchill applications the establishment has implemented to reduce microbial contamination of carcasses.

- Each week collect one pre-evisceration sample to compare results to a matched¹ postchill sample for each of the following microbes: *Salmonella* and Mesophilic Aerobic Bacteria.

NOTE: the alternative daily *Salmonella* testing, weekly Mesophilic Aerobic Bacteria testing, and weekly pre-evisceration to postchill matched samples are used in place of daily postchill generic *E. coli* testing (9 CFR 310.25(a)).

Records all microbiological test results.

Maintains six² or less positive *Salmonella* test results in a 55 sample set by using discrete sample set to count the number of positives to determine status.

Responds to greater than 6 *Salmonella* positive test results by:

- increasing the frequency of *Salmonella* testing to 2 samples per day;
- reviewing the establishment's total food safety system with consideration given to whether the waiver of requirements has caused the lack of control and take corrective and preventive actions to re-gain control and document those actions; and
- demonstrating restoration of process control by conducting at the increased testing frequency two consecutive sample sets that have 6 or less positive *Salmonella* test results in each 55 sample set. After demonstrating control, the frequency of testing can then return to 1 *Salmonella* sample per line per shift.

NOTE: At this time, it is not necessary to send *Salmonella* isolates to the FSIS Laboratory at Athens, Georgia.

Maintains records in the same manner and for the same duration as HACCP records (9 CFR 417.5).

Allows access to the records necessary to document SIP process control including microbiological test results to FSIS IPP. FSIS requires access to the records at least weekly.

Submits microbiological test results to FSIS headquarters monthly according to the FSIS template and instructions on how to submit (including frequency), which can be obtained by e-mailing the FSIS "SIP.Mailbox@FSIS.USDA.gov."

NOTE: Although FSIS expects that an individual establishment submitting data through the template and following instructions will not be identified, FSIS cannot guarantee that data may not be obtained through the Freedom of Information Act (FOIA).

¹ Pre-evisceration and postchill matched samples—postchill taken after time for carcass to travel from pre-evisceration location, through evisceration and cooler.

² Note: The expected level of an establishment's performance is contained in this letter or future SIP letters

Provides FSIS 30 days prior written notice if the establishment decides to stop participation in the SIP and stop operating under the waivers.

Please be aware that if Hormel Foods (Est. M199 N) system conflicts with the provisions of the Federal Meat Inspection Act (21 U.S.C. 601, et seq.), or has repeated Noncompliance Records (NRs) documenting failure to maintain the alternative procedures or to follow the SIP Protocol, then the waivers will be revoked.

If you have questions, please contact Isabel Arrington, Risk, Innovations, and Management Division (RIMD), Office of Policy and Program Development (OPPD) at (402) 344-5016 or e-mail Isabel.Arrington@fsis.usda.gov or Selena Kremer, RIMD, OPPD at (301) 504-0855 or email selena.kremer-caldwell@fsis.usda.gov.

Sincerely,

A handwritten signature in black ink that reads "William K. Shaw, Jr." The signature is written in a cursive, flowing style.

William K. Shaw, Jr.
Director
Risk, Innovations, and Management Division
Office of Policy and Program Development

Attachments:

1. SIP Protocol

cc:

Rachel Edelstein, Acting AA, OPPD

Daniel Engeljohn, AA, OFO

Hany Sidrak, EARO, OFO

Dawn Sprouls, DM, OFO

Khalid Masood, DDM, OFO

Rosemary Turner, DDM, OFO

(b) (6), FLS, OFO

(b) (6), IIC, OFO

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Patrick Burke, RIMD, OPPD

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Liza Murray, RIMD, OPPD

Delila Parham, RIMD, OPPD

Nora Pihkala, RIMD, OPPD

Scott Seys, RIMD, OPPD

Selena Kremer, RIMD, OPPD

FSIS:OPPD:RIMD File: Kremer M199 N SIP Letter Number 11-SIP-128-N-A.



Food Safety and
Inspection Service

December 21, 2016

1400 Independence
Avenue, SW,
Washington, D.C.
20250

Joel Coble
Senior Director Food Safety & Quality Assurance
Tyson Fresh Meats, Inc.,
800 Stevens Port Drive
Dakota Dunes, SD 57049

Dear Mr. Coble:

This letter is in response to your *Salmonella* Initiative Program (SIP) protocol submission dated October 17, 2014 (and assigned Log Number 16-SIP-2041-N-A) at Tyson Fresh Meats, Inc. (Est. M244M); Madison, NE. You have submitted a cover letter and SIP protocol requesting the Food Safety and Inspection Service (FSIS) to grant waivers of 9 CFR 310.11, 310.25 (a) and (b) and in place of the waived regulations to use alternative procedures:

1. to remove certain dressing defects (9 CFR 310.11); and
2. for generic *E. coli* and *Salmonella* sampling and testing [9 CFR 310.25(a) and (b)].

The protocol submitted includes a pre-requisite program (Pork Carcass Prep™) that uses best practices to address and minimize visible hair and other dressing or contamination defects at all components/sections of slaughter dressing. In conjunction with the best practices a process control procedure, In-Process Contamination Audit (IPCA) describes lot acceptance techniques with mandatory control limits and assigning controls in the process to target in process contamination prevention and minimization at the 5 steps in the slaughter process.

In addition, this establishment has been operating at an increased line speed since 1993 based on an internal FSIS memo dated March 18, 1993 addressed to William James from Patrick Burke. The memo describes increased line speeds when kidneys are presented at the viscera inspection station instead of with the carcass. Since the establishment has historically been operating at this line speed (up to (b) (4)) and has been able to maintain process control, this SIP letter supersedes the internal FSIS memo titled Staffing Standards for Swine Inspection with Kidney Inspection at Viscera Station dated March 18, 1993 and will also include the waiver

to 9 CFR 310.1(b)(3). As described in Attachment 2, FSIS SIP Summary and IPP Verification, the Public Health Veterinarian (PHV) is to assess presentation of carcasses to the online inspector at the carcass inspection (CI) station and evaluate the health status of the herd, sanitary dressing process or other factors that may indicate loss of process control, such as persistent unattended defects to determine whether these factors are having any impact on ability of IPP to perform the proper inspection procedures at a given line speed. The PHV is to reduce the line speed at which the online carcass inspector can perform proper inspection (9 CFR 310.1(b)(1) and 303.1(h)).

Background:

The SIP is a voluntary program for meat and poultry slaughter establishments that agree to test for *Salmonella*, *Campylobacter* (if applicable) and indicator organisms and share all sample results and other corresponding process control data with FSIS in order to receive waivers of provisions of the regulations ([76 FR 41186](#), July 13, 2011). Establishments participating in SIP maintain consistent process control for *Salmonella* and use contamination process control verification activities to determine control limits along with *Salmonella* and indicator organism test results.

The protocol submitted includes Pork PREP (Sanitary dressing best practices) and an In Process Audit procedure pre-requisite program to gauge process capability and performance of carcass dressing procedures in relation to carcass cleanliness to consistently monitor changes and control of slaughter hygiene. This In Process Contamination (IPC) audit (Attachment 1) serves as a process control procedure that targets in-process contamination prevention and minimization rather than removal.

Establishments participating in SIP are to maintain consistent process control for *Salmonella* and use sanitary dressing procedures for preventing visible contamination (or ingesta, feces and milk contamination) and include verification activities in addition to determining control limits for *Salmonella* and indicator organism test results.

Waivers granted and Establishment Agreement:

The Food Safety and Inspection Service (FSIS) has completed the review of your requests and is hereby granting your establishment a waiver of the regulations pending the Agency amendment of 9 CFR 310.1(b)(3), 310.11 and 310.25(a) and (b), pursuant to provisions under 9 CFR 303.1(h).

FSIS has no objection to Est. M244M using alternative procedures to remove certain dressing defects in place of 9 CFR 310.11; using alternative procedures for line speed in place of 9 CFR 310.1(b)(3); alternative generic *E. coli* testing in place of 9 CFR 310.25(a); and, as described in its SIP Protocol, using alternative daily *Salmonella* sampling and testing procedures in place of 9 CFR 310.25(b) provided the establishment:

A. Reassesses, modifies and validates as appropriate, the Hazard Analysis and Critical Control Point (HACCP) food safety system (HACCP plan, Sanitation-SOP or other prerequisite program) according to 9 CFR 304.3, 416 and 417.4 for:

1. the SIP protocol;
2. alternative procedures used in place of 9 CFR 310.11 for removing eyelids and eyelash stubble remaining on carcasses after dehairing and first incision by a hole-punch device to ensure that the eyelids on the skull, with any hair present, are removed when the snout is pulled from the head provided; the Pork Carcass PREP best practices (Attachment 1) and the In-Process Contamination (IPC) audit program (Attachment 1) continually demonstrate process control, as per protocols including taking corrective action if control limits are exceeded;
3. alternative procedures used in place of 9 CFR 310.11 for removing incidental carcass hair that is not readily visible (does not require frisking or rubbing the hog to visualize) or exists visually under the dermis layers at locations after first incision provided the Pork Carcass PREP best practices (Attachment 1) and IPC (Attachment 2) continually demonstrate process control, including taking corrective action if control limits are exceeded;
4. Alternative procedures used in place of 9 CFR 310.1(b)(3);
5. Ensures that the post-evisceration, pre-final rail carcass wash at audit step is turned off if carcasses with visible, incidental fecal or oral ingesta or certain pathological conditions are found before the wash (at audit 5 step); and
6. Validates in-plant within 90 days of implementing the alternative procedures for removal of eyelids and eyelash stubble and for removal of not readily visible incidental hairs.

D. Makes available and discusses with FSIS Inspection Program Personnel (IPP) at the weekly meeting this SIP Letter and SIP Protocol including:

1. regulations waived (9 CFR 310.11, 310.25(a) and (b)),

2. alternative procedures the establishment will use in place of each waived regulation,
 3. specified microbiological sampling and testing implemented including records,
 4. the establishment's agreement to share microbiological sampling and testing results with FSIS and
 5. Attachment 2: FSIS SIP Summary and IPP Verification which summarizes IPP verification procedures for verifying that the establishment is operating in a manner that is consistent with the alternative procedures and SIP Protocol.
- E. Conducts microbiological sampling agreed to as condition of receiving the waiver under SIP as follows:
1. Write sampling collection procedures that identify employees 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* and *Enterobacteriaceae* (EB).
 2. Conduct microbiological sampling according to the written sampling procedures and at the frequency stated below:
 - a. Every day of production collect one *Salmonella* sample per line per shift at the postchill location after any postchill antimicrobial intervention applications the establishment has implemented to reduce microbial contamination of carcasses.
 - b. Each week collect one pre-evisceration sample to compare results to a matched¹ postchill sample for each of the following microbes: *Salmonella* and EB.
 3. Record all microbiological test results.
 4. Maintain *Salmonella* process control (currently six² or less positive *Salmonella* test results in a 55 sample set size).

¹ Pre evisceration and postchill matched samples—postchill taken after carcass is chilled in cooler

² Note: The expected level of an establishment's performance is subject to change if the performance standard changes.

5. Evaluate daily *Salmonella* test results by counting the number of positives in a moving window of 55 samples.
6. Respond to greater than six *Salmonella* positive test results in a 55 sample set by:
 - a. Increasing the frequency of *Salmonella* testing to two samples per line per shift (for a total of four samples per day) until 2 consecutive discrete sample sets have six or less positive *Salmonella* test results in each sample set.
 - b. Reviewing the establishment's total food safety system with consideration given to whether the waiver of requirements has caused the lack of control.
 - c. Taking corrective and preventive actions to re-gain control and documenting findings and resulting actions.
 - d. Demonstrating restoration of control following any corrective action by conducting at the increased frequency of testing, 2 consecutive *Salmonella* sample sets of 55 with six or less positive test results per sample set. After demonstrating control, the frequency of testing can then return to 1 *Salmonella* sample per line per shift

NOTE: At this time, it is not necessary to send *Salmonella* isolates to the FSIS Laboratory at Athens, Georgia.

- F. Maintain records in same manner and for the same duration as HACCP records (9 CFR 417.5).
- G. Provide access to the records necessary to document SIP process control, including microbiological test results when requested by FSIS IPP.
- H. Submit microbiological test results to FSIS headquarters monthly according to the FSIS template and instructions on how to submit which can be obtained by e-mailing the FSIS "SIP.Mailbox@FSIS.USDA.gov".

NOTE: Although FSIS expects that an individual establishment submitting data through the template and following instructions will not be identified, FSIS cannot

guarantee that data may not be obtained through the Freedom of Information Act (FOIA).

- I. Provides FSIS 30 days prior written notice if the establishment decides to stop participation in the SIP and stop functioning under the waivers.

IPP Verification Responsibilities:

- A. FSIS Attachment 2. FSIS SIP Summary and IPP Verification provides specific verification procedures that IPP are to use to verify that the establishment is operating in a manner that is consistent with the alternative procedures and SIP Protocol.
- B. IPP are to conduct verification tasks based on how the establishment has incorporated alternative procedures into its food safety system (HACCP plan, Sanitation-SOP or other pre-requisite program) and in accordance with FSIS [Directive 5000.1 Verifying an Establishment's Food Safety System](#).
- C. Once a week IPP are to verify one or more parts of the alternative procedures, SIP sampling and testing and SIP Protocol according to instructions in FSIS [Directive 5020.1 Verification of SIP](#). If the SIP protocol disagrees with the SIP Letter, verify according to the SIP Letter requirements and issue non-compliance records (NRs) as appropriate.
- D. IPP are to verify that the establishment is conducting and implementing the required SIP microbiological sampling and testing according to this SIP letter and SIP Protocol. IPP are to verify that the establishment is;
 1. Conducting microbiological sampling according to written procedures;
 2. Recording and evaluating the test results;
 3. Responding when the allowable number of positives is exceeded by increasing testing frequency until two consecutive sample sets have 5 or less positive *Salmonella* results; and
 4. Investigating the cause and document any corrective actions.
- E. IPP are not to write a noncompliance report (NR) if allowable number of *salmonella* positives is exceeded. IPP are to write NRs when the establishment does not follow alternative procedures authorized by the waiver, doesn't maintain records that reflect its use of those procedure or

doesn't follow sampling and testing written procedures required under SIP. When noncompliance is found IPP are to take appropriate action and follow instructions in [FSIS Directive 5000.1, Ch. V. Documentation and Enforcement](#). IPP are to report through their supervisor channels if he or she observes a trend of repeated NRs related to the alternative procedures or SIP protocol.

Please be aware that if Tyson Fresh Meats, Inc. (Est. M244M) system conflicts with the provisions of the Federal Meat Inspection Act (21 U.S.C. 601, et seq.), or has repeated Noncompliance Records (NRs) documenting failure to maintain the alternative procedures or to follow the SIP Protocol, then the waivers will be revoked.

If you have questions, please contact, Melanie Abley Risk, Innovations, and Management Staff (RIMS), Office of Policy and Program Development (OPPD) at (202) 690-5673 or e-mail Melanie.Abley@fsis.usda.gov .

Sincerely,

A handwritten signature in green ink that reads "William K. Shaw, Jr." with a stylized flourish at the end.

William K. Shaw, Jr.

Director

Risk, Innovations, and Management Staff
Office of Policy and Program Development

Attachments:

1. SIP Protocol and Attachment 1, 2, 3, 4
2. FSIS SIP Summary and IPP Verification

cc:

Daniel Engeljohn, AA, OPPD

William Smith, AA, OFO

Keith Gilmore, EARO, OFO

Anna Gallegos, DM

Maria Esteras, DDM

Robert Reeder, DDM

Richard Atkinson, DDM

(b) (6), FLS

(b) (6), SPHV/IIC

(b) (6), PHV,

Melanie Abley RIMS, OPPD

Scott Seys, RIMS, OPPD

Isabel Arrington, PDS, OPPD

FSIS:OPPD:RIMS File: M244I SIP Letter Number 14-SIP-0162 -N-A.

January 23, 2013

Mr. Joel Coble
Senior Director FSQA
Tyson Fresh Meats, Inc., M00244
800 Stevens Port Dr.
Dakota Dunes, SD 57049

Dear Mr. Coble:

This letter is in response to your *Salmonella* Initiative Program (SIP) protocol submission dated September 1, 2011, (Log Number 11-SIP-008-N-B; this log number supersedes previous log numbers) at Tyson Fresh Meats, Inc. (Est. M244); Storm Lake, IA and your waiver requests for the use of alternative procedures:

- to remove certain dressing defects (9 CFR 310.11);
- to identify and remove bruises (9 CFR 310.14); and
- for generic *E. coli* and *Salmonella* sampling and testing [9 CFR 310.25(a) and (b)].

The Food Safety and Inspection Service (FSIS) has completed the review of your requests and is hereby granting your company a waiver of the regulations pending the Agency amendment of 9 CFR 310.11, 310.14, and 310.25(a) and (b), pursuant under 9 CFR 303.1(h).

In addition FSIS has reviewed your requests for clarification of policy regarding toe notching, reconditioning of heads with ingesta contamination and reconditioning of ears, hearts, heads, and tongues and determined that a waiver of regulations is not necessary.

- Toe notching of every toe is not specifically required by regulation. Establishments may remove dirt or scurf between the toes in a sanitary manner by toe notching, knife trim, or sorting out feet. If scalding, rinsing, and dehairing have removed the dirt or scurf, then notching is not required.
- Heads with ingesta contaminants may be reconditioned in a sanitary manner by flushing with water and an antimicrobial solution. Heads must be identified in a manner that maintains traceability back to the carcass.
- Ears, hearts, heads, and tongues may be reconditioned provided that reconditioning is performed in a sanitary manner and that cut surfaces are trimmed before washing to remove visible contaminants to restore sanitary conditions and prevent further contamination.

FSIS has no objection to Est. M244 using alternative procedures to remove certain dressing defects in place of 9 CFR 310.11; identify and remove bruises in place of 9 CFR 310.14; alternative generic *E. coli* testing in place of 9 CFR 310.25(a); and, as described in its SIP Protocol, using alternative daily *Salmonella* sampling and testing procedures in place of 9 CFR 310.25(b) provided the establishment:

1. Assesses, modifies and validates as appropriate, the Hazard Analysis and Critical Control Point (HACCP) plan according to 9 CFR 304.3 and 417.4 for:
 - the SIP protocol;
 - alternative procedures for removing eyelids and eyelash stubble remaining on carcasses after the dehairing process (and after the first incision) by a hole-punch device that marks the eye and eyelid to ensure that the eyelids on the skull, with any hair present, are removed when the snout is pulled from the head provided the Pork Slaughter Sanitary Dressing Best Practices and Statistical Process Control (SPC) In Process Audit Procedure continually demonstrate process control including taking corrective action if control limits are exceeded in place of 9 CFR 310.11;
 - alternative procedures for removing incidental carcass hair that is not readily visible (does not require frisking or rubbing the hog to visualize) or exists visually under the dermis layers at locations after the first incision provided the Pork Slaughter Sanitary Dressing Best Practices and SPC In Process Audit Procedure continually demonstrate process control, including taking corrective action if control limits are exceeded, in place of 9 CFR 310.11; and
 - alternative procedures for identification and removal of lightly or slightly bruised areas may occur at chilling locations or at other locations in the establishment provided the Pork Slaughter Sanitary Dressing Best Practices and SPC In Process Audit Procedure are demonstrating process control, including taking corrective actions if control limits are exceeded, in place of 9 CFR 310.14.
2. Validates in-plant within 90 days of implementing the alternative procedures for removal of eyelids and eyelash stubble, for removal of not readily visible incidental hairs and for identification and removal of lightly or slightly bruised areas.
3. Makes available and discuss with FSIS Inspection Program Personnel (IPP) at the weekly meeting or on a conference call with IPP and appropriate District Office the following:
 - this SIP Letter which provides that FSIS is granting a waiver of 9 CFR 310.11, 310.14, and 310.25(a) and (b), and has no objection to Est. M244 using the alternative procedures specified in this letter and the SIP Protocol;
 - the alternative procedures the establishment will use as described above;

- the SIP Protocol which identifies the regulations waived, the alternative procedures used, the microbiological sampling and testing implemented and the establishment's agreement to share microbiological sampling and testing results and other data with FSIS; and
- the IPP Verification Overview which:
 - identifies where the establishment has elected to include its alternative procedures and SIP Protocol in its food safety system, and
 - provides specific verification procedures for verifying that the establishment is operating in a manner that is consistent with the alternative procedures and SIP Protocol.

NOTE: IPP are to verify one or more parts of the alternative procedures or other aspects of the SIP Protocol once per week using an appropriate Public Health Inspection System (PHIS) task and according to instructions in FSIS Directive 5020.1 Verification of SIP.

IPP Verification Overview:

<u>Regulation(s) Waived</u>	<u>Alternative Procedures Verified by IPP</u>	<u>Location in Food Safety System</u>	<u>Regulation(s) to Verify and Cite on NR</u>
9 CFR 310.11 (Hair Removal)	Using the alternative procedures for removing eyelids and eyelash stubble remaining on carcasses after the dehairing process (and after the first incision) by a hole-punch device that marks the eye and eyelid to ensure that the eyelids on the skull, with any hair present, are removed when the snout is pulled from the head provided the Pork Slaughter Sanitary Dressing Best Practices and SPC In Process Audit Procedure continually demonstrate process control including investigating and taking corrective actions if control limits are exceeded.	Prerequisite Program	Verify establishment is following alternative procedures 9 CFR 310.11 & 303.1(h)
9 CFR 310.11	Using the alternative	Prerequisite	Verify establishment is

(Hair removal)	procedures for removing incidental carcass hair that is not readily visible (does not require frisking or rubbing the hog to visualize) or exists visually under the dermis layers at a location after the first incision provided the Pork Slaughter Sanitary Dressing Best Practices and SPC In Process Audit Procedure continually demonstrate process control including investigating and taking corrective actions if control limits are exceeded.	Program	following alternative procedures 9 CFR 310.11 & 303.1(h)
9 CFR 310.14 (Handling of bruised parts)	Using the alternative procedures for identification and removal of lightly or slightly bruised areas may occur at chilling locations provided the Pork Slaughter Sanitary Dressing Best Practices and SPC In Process Audit Procedure continually demonstrate process control including investigating and taking corrective actions if control limits are exceeded.	Prerequisite Program	Verify establishment is following alternative procedures 9 CFR 310.14 & 303.1(h)
310.25(b) (<i>Salmonella</i> Performance Standard)	SIP Protocol : Establishment Microbial Testing A. <u>Frequency</u> 1. Daily: <i>Salmonella</i> postchill samples 1 per	Prerequisite Program	Verify establishment is following SIP Protocol and is therefore supporting decisions made in the hazard analysis.

	<p>line per shift</p> <p>2. Weekly: one matched pair samples per day for <i>Salmonella</i>, <i>Enterobacteriaceae</i> (EB)</p> <p>B. <u>Following Sampling and testing procedures</u></p> <p>C. <u>Recording and responding</u> to Daily <i>Salmonella</i> test results;</p> <p>D. <u>If exceed standard:</u></p> <p>1. Increase <i>Salmonella</i> frequency to 2 samples per shift.</p> <p>2. Investigate cause, document corrective actions.</p> <p>3. Return to previous frequency when 2 consecutive sample sets meet standard (no more than 6 positives out of 55 samples).</p>		9 CFR 417.5(a) & 303.1(h)
310.25(a) (<i>E. coli</i> testing frequency)	Generic <i>E. coli</i> frequency is zero.	Alternative frequency is zero.	

4. Writes sampling procedures that identify employees designated to collect samples and address locations of sampling, how random sampling will be achieved to cover all lines and all shifts, and how the samples will be handled to ensure sample integrity for *Salmonella* and applicable indicator organisms [*Enterobacteriaceae* (EB)].
5. Conducts microbiological sampling according to the written sampling procedures and at the frequency stated below:
 - Every day of production collect one *Salmonella* sample per evisceration line per shift (for a total of 2 samples per day) at the postchill location after all postchill applications the establishment has implemented to reduce microbial contamination of carcasses.

- Each week collect one pre-evisceration sample to compare results to a matched¹ postchill sample for each of the following microbes: *Salmonella* and *EB*.

NOTE: the alternative daily *Salmonella* testing and weekly *Salmonella* and *EB* pre-evisceration to postchill matched samples are used in place of daily postchill generic *E. coli* testing [9 CFR 310.25(a)].

6. Records all microbiological test results.
7. Maintains six² or less positive *Salmonella* test results in a 55 sample set by using discrete sample set to count the number of positives to determine status.
8. Responds to greater than 6 *Salmonella* positive test results by:
 - increasing the frequency of *Salmonella* testing to 4 samples per day;
 - reviewing the establishment's total food safety system with consideration given to whether the waiver of requirements has caused the lack of control and take corrective and preventive actions to re-gain control and document those actions; and
 - demonstrating restoration of process control by conducting at the increased testing frequency two consecutive sample sets that have 6 or less positive *Salmonella* test results in each 55 sample set. After demonstrating control, the frequency of testing can then return to 1 *Salmonella* sample per line per shift.

NOTE: At this time, it is not necessary to send *Salmonella* isolates to the FSIS Laboratory at Athens, Georgia.

9. Maintains records in the same manner and for the same duration as HACCP records (9 CFR 417.5).
10. Allows access to the records necessary to document SIP process control including microbiological test results to FSIS IPP. FSIS requires access to the records at least weekly.
11. Submits microbiological test results to FSIS headquarters monthly according to the FSIS template and instructions on how to submit (including frequency), which can be obtained by e-mailing the FSIS "SIP.Mailbox@FSIS.USDA.gov."

NOTE: Although FSIS expects that an individual establishment submitting data through the template and following instructions will not be identified, FSIS cannot guarantee that data may not be obtained through the Freedom of Information Act (FOIA).

¹ Pre-evisceration and postchill matched samples—postchill taken after time for carcass to travel from pre-evisceration location, through evisceration and cooler.

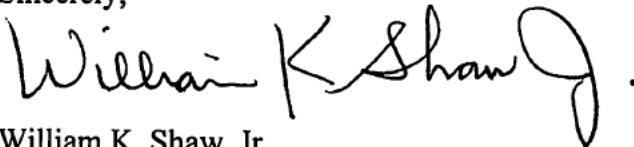
² Note: The expected level of an establishment's performance is contained in this letter or future SIP letters

12. Provides FSIS 30 days prior written notice if the establishment decides to stop participation in the SIP and stop operating under the waivers.

Please be aware that if Tyson Fresh Meats, Inc. (Est. M244) system conflicts with the provisions of the Federal Meat Inspection Act (21 U.S.C. 601, et seq.), or has repeated Noncompliance Records (NRs) documenting failure to maintain the alternative procedures or to follow the SIP Protocol, then the waivers will be revoked.

If you have questions, please contact Isabel Arrington, Risk, Innovations, and Management Division (RIMD), Office of Policy and Program Development (OPPD) at (402) 344-5016 or e-mail Isabel.Arrington@fsis.usda.gov or Selena Kremer, RIMD, OPPD at (301) 504-0855 or email selena.kremer-caldwell@fsis.usda.gov.

Sincerely,



William K. Shaw, Jr.
Director
Risk, Innovations, and Management Division
Office of Policy and Program Development

Attachments:

1. SIP Protocol
2. In Process Control Audit

cc:

Rachel Edelstein, AA, OPPD
Daniel Engeljohn, AA, OFO
Hany Sidrak, EARO, OFO
Dawn Sprouls, DM, OFO
Todd Gerwig, DDM, OFO
Rosemary Turner, DDM, OFO
Khalid Masood, DDM, OFO
(b) (6) FLS, OFO
(b) (6) IIC, OFO
Patrick Burke, RIMD, OPPD
Isabel Arrington, RIMD, OPPD
Liza Murray, RIMD, OPPD
Delila Parham, RIMD, OPPD
Nora Pihkala, RIMD, OPPD
Scott Seys, RIMD, OPPD
Selena Kremer, RIMD, OPPD

FSIS:OPPD:RIMD File: M244 SIP Letter Number 11-SIP-008-N-B.

October 11, 2012

Mr. Kevin Mead
Director of QA and Technical Services
Clougherty Packing, LLC, M360
3409 E. Vernon Avenue
Los Angeles, CA 90058

Dear Mr. Mead:

This letter is in response to your *Salmonella* Initiative Program (SIP) protocol submission dated November 7, 2011, (Log Number 11-SIP-129-N-B which supersedes all other log numbers) at Clougherty Packing, LLC (Est. M360); Los Angeles, CA and your waiver requests for the use of alternative:

- procedures for line speed and HACCP-based Inspection Models Project (HIMP) [9 CFR 310.1(b)(3)]; and
- procedures for generic *E. coli* and *Salmonella* sampling and testing [9 CFR 310.25(a) and (b)].

The Food Safety and Inspection Service (FSIS) has completed the review of your requests and is hereby granting your company an approval of the waiver of the regulations pending the Agency amendment of 9 CFR 310.1(b)(3) and 310.25(a) and (b), pursuant under 9 CFR 303.1(h).

FSIS has no objection to Est. M360 using alternative procedures for line speed in place of 9 CFR 310.1(b)(3), alternative generic *E. coli* sampling and testing in place of 9 CFR 310.25(a), and alternative daily *Salmonella* sampling and testing procedures as described in its SIP Protocol in place of 9 CFR 310.25(b) provided the establishment:

Assesses, modifies and validates as appropriate, the Hazard Analysis and Critical Control Point (HACCP) plan according to 9 CFR 304.3 and 417.4 for:

- the SIP protocol;
- continuing CCPs for Infectious conditions (e.g. pyemia, septicemia, toxemia) (9 CFR 311.16 and 311.17), for Contamination (fecal, ingesta and milk contamination) [(9 CFR 310.11 and 310.18(a)], and for Ante-mortem Suspect (9 CFR 309.2) with zero as the critical limit (CL); and

- continuing the Slaughter Process Control Plan to meet standards of the FSIS “Market Hogs HIMP” Draft dated 06/21/05; and the alternative procedures for line speed [9 CFR 310.1(b)(3)].

Makes available and discuss with FSIS Inspection Program Personnel (IPP) at the weekly meeting or on a conference call with IPP and appropriate District Office the following:

- this SIP Letter which provides that FSIS is granting a waiver of 9 CFR 310.1(b)(3) and 310.25(a) and (b) and has no objection to Est. M360 using the alternative procedures specified in this letter and the SIP Protocol;
- the alternative procedures the establishment will use as described above;
- the SIP Protocol which identifies the regulations waived, the alternative procedures used, the microbiological sampling and testing implemented and the establishment’s agreement to share microbiological sampling and testing results and other data with FSIS; and
- the IPP Verification Overview which:
 - identifies where the establishment has elected to include its alternative procedures and SIP Protocol in its food safety system, and
 - provides specific verification procedures for verifying that the establishment is operating in a manner that is consistent with the alternative procedures and SIP Protocol.
 - NOTE:** IPP are to verify one or more parts of the alternative procedures or other aspects of the SIP Protocol once per week using an appropriate Public Health Inspection System (PHIS) task and according to instructions in FSIS Directive 5020.1 Verification of SIP.

IPP Verification Overview:

<u>Regulation(s) Waived</u>	<u>Alternative Procedures Verified by IPP</u>	<u>Location in Food Safety System</u>	<u>Regulation(s) to Verify and Cite on NR</u>
310.1(b)(3) (line speed)	HIMP Slaughter Process Control Plan Establishment conducts monitoring according to plan and meets requirements of FSIS – Market Hogs HIMP Draft (06/21/05).	Prerequisite Program	Verify according to FSIS – Market Hogs HIMP Draft (06/21/05) 303.1(h)

310.25(b) (<i>Salmonella</i> Performance Standard)	SIP Protocol : Establishment Microbial Testing A. Frequency 1. <u>Daily:</u> <i>Salmonella</i> postchill samples 1 per line per shift 2. <u>Weekly:</u> one matched pair samples per plant for <i>Salmonella, Mesophilic</i> <i>Aerobic Bacteria</i> B. <u>Following Sampling and</u> <u>testing procedures</u> C. <u>Recording and</u> <u>responding to Daily</u> <u><i>Salmonella</i> test results;</u> D. <u>If exceed standard:</u> 1. Increase <i>Salmonella</i> <i>frequency</i> to 2 samples per shift. 2. Investigate cause, document corrective actions. 3. Return to previous frequency when 2 consecutive sample sets meet standard (no more than 6 positives out of 55 samples).	Prerequisite Program	Verify establishment is following SIP Protocol and is therefore supporting decisions made in the hazard analysis. 417.5(a) & 303.1(h)
310.25(a) (<i>E. coli</i> testing frequency)	(Generic <i>E. coli</i> frequency is zero).		

Writes sampling procedures that identify employees designated to collect samples and address locations of sampling, how random sampling will be achieved to cover all lines and all shifts, and how the samples will be handled to ensure sample integrity for *Salmonella* and applicable indicator organisms (Mesophilic Aerobic Bacteria).

Conducts microbiological sampling according to the written sampling procedures and at the frequency stated below:

- Every day of production collect one *Salmonella* sample per evisceration line per shift (for a total of 1 sample per day) at the postchill location after all postchill applications the establishment has implemented to reduce microbial contamination of carcasses.

- Each week collect one pre-evisceration sample to compare results to a matched¹ postchill sample for each of the following microbes: *Salmonella* and Mesophilic Aerobic Bacteria.

NOTE: the alternative daily *Salmonella* testing, weekly Mesophilic Aerobic Bacteria testing, and weekly pre-evisceration to postchill matched samples are used in place of daily postchill generic *E. coli* testing (9 CFR 310.25(a)).

Records all microbiological test results.

Maintains six² or less positive *Salmonella* test results in a 55 sample set by using discrete sample set to count the number of positives to determine status.

Responds to greater than 6 *Salmonella* positive test results by:

- increasing the frequency of *Salmonella* testing to 2 samples per day;
- reviewing the establishment's total food safety system with consideration given to whether the waiver of requirements has caused the lack of control and take corrective and preventive actions to re-gain control and document those actions; and
- demonstrating restoration of process control by conducting at the increased testing frequency two consecutive sample sets that have 6 or less positive *Salmonella* test results in each 55 sample set. After demonstrating control, the frequency of testing can then return to 1 *Salmonella* sample per line per shift.

NOTE: At this time, it is not necessary to send *Salmonella* isolates to the FSIS Laboratory at Athens, Georgia.

Maintains records in the same manner and for the same duration as HACCP records (9 CFR 417.5).

Allows access to the records necessary to document SIP process control including microbiological test results to FSIS IPP. FSIS requires access to the records at least weekly.

Submits microbiological test results to FSIS headquarters monthly according to the FSIS template and instructions on how to submit (including frequency), which can be obtained by e-mailing the FSIS "SIP.Mailbox@FSIS.USDA.gov."

NOTE: Although FSIS expects that an individual establishment submitting data through the template and following instructions will not be identified, FSIS cannot guarantee that data may not be obtained through the Freedom of Information Act (FOIA).

¹ Pre-evisceration and postchill matched samples—postchill taken after time for carcass to travel from pre-evisceration location, through evisceration and cooler.

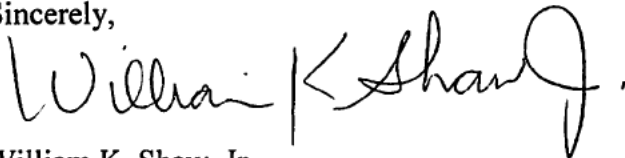
² Note: The expected level of an establishment's performance is contained in this letter or future SIP letters

Provides FSIS 30 days prior written notice if the establishment decides to stop participation in the SIP and stop operating under the waivers.

Please be aware that if Clougherty Packing, LLC (Est. M360) system conflicts with the provisions of the Federal Meat Inspection Act (21 U.S.C. 601, et seq.), or has repeated Noncompliance Records (NRs) documenting failure to maintain the alternative procedures or to follow the SIP Protocol, then the waivers will be revoked.

If you have questions, please contact Isabel Arrington, Risk, Innovations, and Management Division (RIMD), Office of Policy and Program Development (OPPD) at (402) 344-5016 or e-mail Isabel.Arrington@fsis.usda.gov or Selena Kremer, RIMD, OPPD at (301) 504-0855 or email selena.kremer-caldwell@fsis.usda.gov.

Sincerely,



William K. Shaw, Jr.
Director
Risk, Innovations, and Management Division
Office of Policy and Program Development

Attachments:

1. SIP Protocol

cc:

Rachel Edelstein, Acting AA, OPPD
Daniel Engeljohn, AA, OFO
Hany Sidrak, EARO, OFO
Yudhbir Sharma, DM, OFO
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Selena Kremer, RIMD, OPPD

FSIS:OPPD:RIMD File: Kremer M360 SIP Letter Number 11-SIP-129-N-B.

September 19, 2014

Mr. Joel Coble
Senior Director Food Safety & Quality Assurance
Food Safety and Regulatory Compliance Manager
Tyson Fresh Meats, Inc., M244W
800 Stevens Port Drive
Dakota Dunes, SD 57049

Dear Mr. Coble:

This letter is in response to your *Salmonella* Initiative Program (SIP) protocol submission dated May 27, 2014, (Log Number 14-SIP-0158-N-A) at Tyson Fresh Meats, Inc. (Est. M244W); Waterloo, IA and your waiver requests for the use of alternative procedures:

- to remove certain dressing defects (9 CFR 310.11); and
- for generic *E. coli* and *Salmonella* sampling and testing [9 CFR 310.25(a) and (b)].

The Food Safety and Inspection Service (FSIS) has completed the review of your requests and is hereby granting your company a waiver of the regulations pending the Agency amendment of 9 CFR 310.11 and 310.25(a) and (b), pursuant under 9 CFR 303.1(h).

FSIS has no objection to Est. M244W using alternative procedures to remove certain dressing defects in place of 9 CFR 310.11; alternative generic *E. coli* testing in place of 9 CFR 310.25(a); and, as described in its SIP Protocol, using alternative daily *Salmonella* sampling and testing procedures in place of 9 CFR 310.25(b) provided the establishment:

1. Assesses, modifies and validates as appropriate, the Hazard Analysis and Critical Control Point (HACCP) plan according to 9 CFR 304.3 and 417.4 for:
 - the SIP protocol;
 - alternative procedures for removing eyelids and eyelash stubble remaining on carcasses after the dehairing process (and after the first incision) by a hole-punch device that marks the eye and eyelid to ensure that the eyelids on the skull, with any hair present, are removed when the snout is pulled from the head provided the In Process Audit Procedure continually demonstrate process control including taking corrective action if control limits are exceeded in place of 9 CFR 310.11;
 - alternative procedures for removing incidental carcass hair that is not readily visible (does not require frisking or rubbing the hog to visualize) or exists visually under the dermis layers at locations after the first incision provided the In Process Audit

Procedure continually demonstrate process control, including taking corrective action if control limits are exceeded, in place of 9 CFR 310.11; and

2. Ensures that the post-evisceration, pre-final rail carcass wash is turned off if carcasses with visible, incidental fecal or oral ingesta or certain pathological conditions are found before the wash.
3. Validates in-plant within 90 days of implementing the alternative procedures for removal of eyelids and eyelash stubble and for removal of not readily visible incidental hairs.
4. Makes available and discuss with FSIS Inspection Program Personnel (IPP) at the weekly meeting or on a conference call with IPP and appropriate District Office the following:
 - this SIP Letter which provides that FSIS is granting a waiver of 9 CFR 310.11 and 310.25(a) and (b), and has no objection to Est. M244W using the alternative procedures specified in this letter and the SIP Protocol;
 - the alternative procedures the establishment will use as described above;
 - the SIP Protocol which identifies the regulations waived, the alternative procedures used, the microbiological sampling and testing implemented and the establishment's agreement to share microbiological sampling and testing results and other data with FSIS; and
 - the IPP Verification Overview which:
 - identifies where the establishment has elected to include its alternative procedures and SIP Protocol in its food safety system, and
 - provides specific verification procedures for verifying that the establishment is operating in a manner that is consistent with the alternative procedures and SIP Protocol.

NOTE: IPP are to verify one or more parts of the alternative procedures or other aspects of the SIP Protocol once per week using an appropriate Public Health Inspection System (PHIS) task and according to instructions in FSIS Directive 5020.1 Verification of SIP.

IPP Verification Overview:

<u>Regulation(s) Waived</u>	<u>Alternative Procedures Verified by IPP</u>	<u>Location in Food Safety System</u>	<u>Regulation(s) to Verify and Cite on NR</u>
9 CFR 310.11 (Hair Removal)	Using the alternative procedures for removing eyelids and eyelash stubble remaining on carcasses after the dehairing process (and	Prerequisite Program	Verify establishment is following alternative procedures 9 CFR 310.11 & 303.1(h)

	after the first incision) by a hole-punch device that marks the eye and eyelid to ensure that the eyelids on the skull, with any hair present, are removed when the snout is pulled from the head provided the In Process Audit Procedure continually demonstrate process control including investigating and taking corrective actions if control limits are exceeded.		
9 CFR 310.11 (Hair removal)	Using the alternative procedures for removing incidental carcass hair that is not readily visible (does not require frisking or rubbing the hog to visualize) or exists visually under the dermis layers at a location after the first incision provided the In Process Audit Procedure continually demonstrate process control including investigating and taking corrective actions if control limits are exceeded.	Prerequisite Program	Verify establishment is following alternative procedures 9 CFR 310.11 & 303.1(h)
310.25(b) (<i>Salmonella</i> Performance Standard)	SIP Protocol : Establishment Microbial Testing A. <u>Frequency</u> 1. <u>Daily</u> : <i>Salmonella</i> postchill samples 1 per line per shift 2. <u>Weekly</u> : one matched pair samples per day for <i>Salmonella</i> , <i>Enterobacteriaceae</i> (EB)	Prerequisite Program	Verify establishment is following SIP Protocol and is therefore supporting decisions made in the hazard analysis. 417.5(a) & 303.1(h)

	<p><u>B. Following Sampling and testing procedures</u></p> <p><u>C. Recording and responding to Daily <i>Salmonella</i> test results;</u></p> <p><u>D. If exceed standard:</u></p> <ol style="list-style-type: none"> 1. Increase <i>Salmonella</i> frequency to 2 samples per shift. 2. Investigate cause, document corrective actions. 3. Return to previous frequency when 2 consecutive sample sets meet standard (no more than 6 positives out of 55 samples). 		
310.25(a) (<i>E. coli</i> testing frequency)	Generic <i>E. coli</i> frequency is zero.	Alternative frequency is zero.	

- Writes sampling procedures that identify employees designated to collect samples and address locations of sampling, how random sampling will be achieved to cover all lines and all shifts, and how the samples will be handled to ensure sample integrity for *Salmonella* and applicable indicator organisms [*Enterobacteriaceae* (*EB*)].
- Conducts microbiological sampling according to the written sampling procedures and at the frequency stated below:
 - Every day of production collect one *Salmonella* sample per evisceration line per shift (for a total of 1 sample per day) at the postchill location after all postchill applications the establishment has implemented to reduce microbial contamination of carcasses.
 - Each week collect one pre-evisceration sample to compare results to a matched¹ postchill sample for each of the following microbes: *Salmonella* and *EB*.

NOTE: the alternative daily *Salmonella* testing and weekly *Salmonella* and *EB* pre-evisceration to postchill matched samples are used in place of daily postchill generic *E. coli* testing [9 CFR 310.25(a)].

¹ Pre-evisceration and postchill matched samples—postchill taken after time for carcass to travel from pre-evisceration location, through evisceration and cooler.

7. Records all microbiological test results.
8. Maintains six² or less positive *Salmonella* test results in a 55 sample set by using discrete sample set to count the number of positives to determine status.
9. Responds to greater than 6 *Salmonella* positive test results by:
 - increasing the frequency of *Salmonella* testing to 2 samples per day;
 - reviewing the establishment's total food safety system with consideration given to whether the waiver of requirements has caused the lack of control and take corrective and preventive actions to re-gain control and document those actions; and
 - demonstrating restoration of process control by conducting at the increased testing frequency two consecutive sample sets that have 6 or less positive *Salmonella* test results in each 55 sample set. After demonstrating control, the frequency of testing can then return to 1 *Salmonella* sample per line per shift.

NOTE: At this time, it is not necessary to send *Salmonella* isolates to the FSIS Laboratory at Athens, Georgia.

10. Maintains records in the same manner and for the same duration as HACCP records (9 CFR 417.5).
11. Allows access to the records necessary to document SIP process control including microbiological test results to FSIS IPP. FSIS requires access to the records at least weekly.
12. Submits microbiological test results to FSIS headquarters monthly according to the FSIS template and instructions on how to submit (including frequency), which can be obtained by e-mailing the FSIS "SIP.Mailbox@FSIS.USDA.gov."

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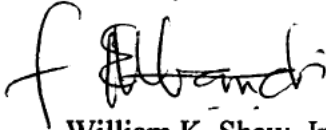
13. Provides FSIS 30 days prior written notice if the establishment decides to stop participation in the SIP and stop operating under the waivers.

Please be aware that if Tyson Fresh Meats, Inc. (Est. M244W) system conflicts with the provisions of the Federal Meat Inspection Act (21 U.S.C. 601, et seq.), or has repeated Noncompliance Records (NRs) documenting failure to maintain the alternative procedures or to follow the SIP Protocol, then the waivers will be revoked.

² Note: The expected level of an establishment's performance is contained in this letter or future SIP letters

If you have questions, please contact Isabel Arrington, Risk, Innovations, and Management Staff (RIMS), Office of Policy and Program Development (OPPD) at (402) 344-5016 or e-mail Isabel.Arrington@fsis.usda.gov or Scott Seys, RIMS, OPPD at (612) 659-7053 or email scott.seys@fsis.usda.gov.

Sincerely,



William K. Shaw, Jr.
Director
Risk, Innovations, and Management Staff
Office of Policy and Program Development

Attachments:

1. SIP Protocol
2. In Process Control Audit

cc:

Daniel Engeljohn, AA, OPPD
William Smith, AA, OFO
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Dawn Sprouls, DM, OFO
Todd Gerwig, DDM, OFO
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FSIS:OPPD:RIMS File: M244W SIP Letter Number 14-SIP-0158-N-A.