



March 11, 2019

Dr. Bryan Trout
USDA/FSIS
Email To: bryan.trout@fsis.usda.gov

Dear Dr. Trout:

RE: Proposed Beef Modernization Protocol Plant Request – Tyson 278

Background - USDA-FSIS began assessing new approaches to slaughter inspection based on Hazard Analysis and Critical Control Point Systems (HACCP) principles shortly after publishing the Pathogen Reduction/ HACCP rule in 1996. In 1997, the Agency developed the HACCP-Based Inspection Models Project (HIMP) study to determine whether applying new slaughter inspection procedures, along with increasing plant responsibilities, could promote innovation and provide at least the same food safety and consumer protection. USDA-FSIS initiated the HIMP study in twenty young chicken, five young turkey, and five market swine establishments on a waiver basis.

In 2016, the Agency proposed to amend federal meat inspection regulations to establish a new optional inspection system for market swine slaughter establishments. The New Swine Inspection System (NSIS) was based on the Agency's experiences under HIMP (Docket No. FSIS-2016-0017). USDA-FSIS proposed this new inspection system to facilitate pathogen reduction in pork products; improve compliance with the Humane Methods of Slaughter Act (HMSA); improve the effectiveness of market hog slaughter inspection; make better use of the Agency's resources; and remove unnecessary regulatory obstacles to innovation by revoking maximum line speeds and allowing establishments flexibility to reconfigure evisceration lines.

The cattle slaughter industry has evolved since the advent of the current cattle inspection regulations used by the USDA-FSIS. Many of today's producers and harvest establishments have invested in farm-to-table food safety, animal care and quality controls. Assessing new approaches to HACCP based slaughter inspection systems is congruent with the industry's, and the agency's desire to drive continuous improvement in the pillars of food safety, environmental and economic sustainability and animal welfare stewardship, while providing safe, healthy food products aligned with consumer expectations.

Cattle slaughter establishments have not, and are not currently, operating under HIMP. As such, pursuant to 9 CFR § 303, we respectfully request permission to modify the beef slaughter system at Tyson Fresh Meats, Inc., Establishment 278, Holcomb, KS facility through regulatory waivers. This regulatory waiver request proposes company team members take over post-mortem pre-sortation activities, including identification and trimming of isolated defects, and identification of conditions that would require additional disposition by the Public Health Veterinarian (PHV). During the waiver period, data will be collected and



made available for FSIS-USDA review to measure the effectiveness of the new HACCP based slaughter inspection system.

Purpose

The purpose of the waivers request is to explore and implement alternative methods of post-mortem inspection which provide equivalent outcomes to current inspection methodologies. The waiver request includes provisions to:

- continue work towards pathogen reduction in beef products;
- continue compliance with the Humane Methods of Slaughter Act (HMSA);
- allow better use of Agency's resources; and
- consider regulatory reform to promote innovation in the industry.

The requested waivers will not adversely affect product safety, jeopardize the safety of inspection or company personnel,

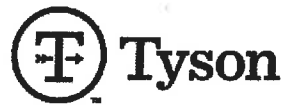
Summary of Request – As outlined below, slaughter procedures would be modified through regulatory waivers discussed in detail in the following sections. The modifications include the use of company team members to perform pre-sortation of carcasses and parts to identify potential food safety or disease conditions that may disqualify the carcass unit from bearing the marks of inspection. This modification would reduce the number of USDA-FSIS inspectors present on the line for post-mortem sortation activities. Currently the Holcomb, KS facility operates a slaughter/ evisceration line for (b) (4) shifts, (b) (4) per week. The line operates at (b) (4) maximum line speed using traditional de-hiding and evisceration operations for a total production volume of approximately (b) (4) or (b) (4) day work week.

Regulatory Authority for Modernization and Regulations to be Waived – 9 CFR § 303.2

Experimentation – Intensity of inspection coverage states in part:

“the frequency with which and the manner in which meat food products made from livestock previously slaughtered in official establishments are examined and inspected by Program employees is to be based on considerations relevant to effective regulation of meat food products and protection of the health and welfare of consumers. In order to test procedures for use in making such determinations and, in particular, for determining whether and, if so, to what extent the intensity of inspection coverage exceeds that which should be considered necessary pursuant to section 6 of the Act, as amended by section 403(a) of the Futures Trading Act of 1986, the Administrator is initiating experimentation of a new system of inspection for reviewing the performance of establishments and for designing the supervision and other conditions and methods of inspection coverage. For the period of such experimentation, the Administrator shall identify establishments for review, and the frequency and the manner of inspection by Program employees shall be determined on the basis of the results of those reviews and be otherwise in accordance with this section.”

Therefore, USDA-FSIS may waive regulatory requirements to permit adoption of a new system of inspection provided that such waiver does not conflict with the Federal Meat Inspection Act (FMIA). Performance and design of the new inspection system would be subject to FSIS – USDA review.



We respectfully request waivers to the following regulations:

- 9 CFR § 310.1(b)(1): states in part *“Staffing standards on the basis of the number of carcasses to be inspected per hour are outlined in the following tables.”*
 - 9 CFR § 310.1(b)(2)(iii) (table) *inspector staffing by station for slaughter rates for inspection using viscera table and tongue-out presentation of heads.* The regulation and table are prescriptive in nature and do not allow flexibility in staffing standards to maximize utilization of space and labor.
 - In this proposal Tyson team members perform pre-sortation, identification and trimming of defects at the head, viscera and carcass stations prior to USDA-FSIS inspector’s post-mortem inspection. The staffing requirement to safely and effectively conduct pre-sortation activities would be determined by operating conditions. Flexibility in this standard will allow fluidity to adjust as necessary based immediate needs and maximize safe, effective and efficient use of labor and space. We request this section of 9 CFR § 310.1(b)(1): and table 9 CFR § 310.1(b)(2)(iii) be waived.

NOTE: As a note of transparency, our intent is to maintain the current daily harvest levels of (b) (4), therefore a waiver to 9 CFR 310.1(b)(1) will not significantly impact the harvest number. We will routinely assess and adjust our line speed to operate a process in-control regarding food safety and animal welfare systems. Furthermore, a fully visible digital read out of line speed is available for USDA-FSIS and company team members to view near the evisceration inspection station. USDA- FSIS inspection can easily access the line speed at any the harvest floor is operating. We shall record and document line speed within our process control records to provide historical framework as coupled with our food safety results. This data is available on-site upon USDA- FSIS request.

- 9 CFR § 307.2(m)(1) *“inspection station consisting of five feet of unobstructed line space for each head or carcass inspector, and eight feet for each viscera inspector on the inspector’s side of the table.”* The prescriptive nature of the space requirements prohibits the exploration of alternate methodologies or technologies to identify more efficient means to perform pre-sortation activities. Allowing the freedom to determine the necessary unobstructed space required to safely and effectively conduct post-mortem pre-sortation activities will maximize efficient use of facility space, provide opportunities to incorporate new technologies and drive innovation. We request 9 CFR § 307.2(m)(1) be waived.
- 9 CFR § 310.14 Handling of Bruised Parts states *“When only a portion of a carcass is to be condemned on account of slight bruises, either the bruised portion shall be removed immediately and disposed of in accordance with part 314 of this subchapter, or the carcass shall be promptly placed in a retaining room and kept until chilled and the bruised portion shall then be removed and disposed of as provided in part 314 of this subchapter.”* Bruises of a food safety concern are addressed by 9 CFR § 311.14 and are addressed as required by that regulation - *“Any organ or other part of a carcass which is badly bruised or which is affected by an abscess, or a suppurating sore shall be condemned...”*



Slight bruises, such as those addressed by 9 CFR § 310.14 are a quality defect and do not pose a direct food safety concern. Immediate removal of tissues with a slight bruise results in uneven surfaces, folds and flaps creating potential to decrease the effectiveness of downstream antimicrobial interventions. Furthermore, immediate removal of a quality defect on the harvest floor has potential to exposes team members to unnecessary safety risks. Allowing the flexibility to remove slight bruises on the fabrication floor, post-chilling prior to packaging, provides opportunity for better antimicrobial intervention application during the harvest process, chilling, while lowering potential safety exposures to harvest floor team members. Effectiveness of this process will be measured at packaging as part of finished product standards for quality defects. For these reasons, we request that CFR § 310.14 be waived.

HACCP Plan –

A hazard analysis of the Slaughter and Raw Not Ground Variety Meat processes has been performed and updated to identify potential food safety hazards associated with company team members performing pre-sortation activities. These potential food safety hazards include, at the outset of this program, (b) (4).

Example of Hazard Analysis:

Process Step	Potential Hazard	RLTO	Justification	Control Measure	CCP?
(b) (4)	(b) (4)	■	(b) (4)	(b) (4)	■
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	
(b) (4)	(b) (4)		(b) (4)	(b) (4)	

Implementation – Tyson Fresh Meats respectfully requests that these waivers be initiated at a time as agreed upon by USDA-FSIS and Tyson Fresh Meats management, following a period of necessary training.



Protocol

a) **Eligibility**

In accordance with 9 CFR § 303, participation in regulatory waivers are open to all federally inspected establishments.

(b) **Requested Inspector Staffing**

The proposed changes to the existing slaughter system will impact (i.e., reduce) the number of line inspectors required to conduct post mortem inspection. We shall staff positions at head inspection, viscera inspection and final carcass inspection stations to pre-sort for conditions requiring further disposition by USDA-FSIS.

Tyson team members conducting pre-sortation activities at the head, viscera and carcass stations will be trained through a certification process that involves class-room instruction, onsite production floor training, qualification, and routine verification. Trained team members will pre-sort carcasses and parts showing signs of food safety defects (i.e. (b) (4) [REDACTED]) and mark the carcass (and parts) for the appropriate disposition by USDA-FSIS per 9 CFR 311. Trained team members will pre-sort carcasses and parts with diseases and conditions not directly associated with food safety (Other Consumer Protection - OCP) but that require sorting, trimming, or disposal depending on the nature, degree, or extent of the condition. At the outset of this program OCP defects will include conditions identified in FSIS Directive 6100.6 - Post-Mortem Dispositions for PHV. Carcasses and associated head and viscera will be marked as needed for appropriate USDA-FSIS disposition.

Trained Tyson management or management designee team members shall verify pre-sorting activities. Verification will be completed on (b) (4) [REDACTED]. The purpose of the verification activity is to provide feedback to pre-sorters. These verification data for FS/ OCP conditions shall be maintained on-site and made available upon request.

FMIA §604. Post mortem examination of carcasses and marking or labeling; destruction of carcasses condemned; reinspection requirement states in part;

For the purposes hereinbefore set forth the Secretary shall cause to be made by inspectors appointed for that purpose a post mortem examination and inspection of the carcasses and parts thereof of all amenable species to be prepared at any slaughtering, meat-canning, salting, packing, rendering, or similar establishment in any State, Territory, or the District of Columbia as articles of commerce which are capable of use as human food; and the carcasses and parts thereof of all such animals found to be not adulterated shall be marked, stamped, tagged, or labeled as "Inspected and passed"; and said inspectors shall label, mark, stamp, or tag as "Inspected and condemned" all carcasses and parts thereof of animals found to be adulterated; and all carcasses and parts thereof thus inspected and condemned shall be destroyed for food purposes by the said establishment in the presence of an inspector,"



To maintain compliance with FMIA §604 during implementation of the new inspection system, the following USDA-FSIS staffing request for the harvest floor, consisting of (b) (4) USDA-FSIS personnel, will be submitted as part of this regulatory waiver application.

- (b) (4)
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

(b) (4)

Carcasses and parts showing indications of food safety or disease conditions that may result in condemnation will be identified with a unique tag to associate all parts with the carcass. Records will be maintained documenting the total number of carcasses pre-sorted for potential condemnable conditions, and ultimate disposition by USDA-FSIS.

[Attachments 1 & 2]

(c) Sanitary Dress

The implementation of existing, comprehensive written sanitary dressing and process control procedures as outlined in our HACCP system will continue:

- a) The Carcass Sanitary Intelligence (CSI) Sanitary Dressing Pre-requisite program provides team member instructions and mechanical equipment settings to prevent and minimize contamination from occurring throughout the slaughter and dressing operation and thereby preventing the creation of insanitary conditions.
- b) The In-Process Contamination (IPC) Pre-requisite program serves as a process control procedure to evaluate slaughter dressing performance¹. Monitoring is conducted for contamination transfer at specific points in the production process to provide timely feedback to the slaughter system.

¹ FSIS Directive 6410.1 defines *Process Control Procedure*: A defined procedure or set of procedures designed by an establishment to provide control of those operating conditions that are necessary for the production of safe, wholesome food. The procedures typically include some means of observing or measuring system performance, analyzing the results generated in order to define a set of control criteria, and taking action when necessary to ensure that the system continues to perform within the control criteria. The procedure is likely to include planned measures that the establishment will take in response to any loss of process control. In addition, the procedures can be used as support for decisions made in the hazard analysis.



Daily written records shall be maintained, available on-site to USDA-FSIS inspection review, to document the implementation and monitoring of its sanitary dressing and process control procedures. These pre-requisite programs are identified in the hazard analyses of the Slaughter and Raw Not Ground Variety Meats HACCP programs to minimize and prevent enteric pathogens (including pathogenic Shiga toxin-producing *Escherichia coli*, or pSTEC) through the slaughter and dressing operation. The established Critical Control Points of (b) (4)

[REDACTED], ensure that the food safety hazards of enteric pathogens (including pSTEC) are controlled to non-detectable levels in finished products.

[Attachments 3-6]

(d) Data Collection

Data will be collected to support the equivalence of our beef modernization program to traditional inspection systems. This data would include:

1. Validated Antimicrobial Intervention Monitoring Data- In accordance with the requirements of 9 CFR 417.4(a)(1), validated antimicrobial intervention CCPs to prevent, eliminate, or reducing pathogens to an undetectable level under the operating conditions are in place. The effectiveness of individual antimicrobial intervention treatments can be demonstrated by ensuring the application to control hazards at the CCP are implemented in a manner that is consistent with the parameters of any scientific, peer-reviewed, published studies, or challenge studies being used as support for decisions in the hazard analysis. The validated intervention CCPs are monitored (b) (4) to ensure critical operating parameters are within the validated parameters during (b) (4) harvest operations. Intervention data is routinely documented from our CCP monitoring and is available for review on-site. [Attachments 3e and 4e]
2. Process Control Sampling and Analysis for Microbial Organisms - Slaughter dressing process control will be monitored by sampling for generic *E. coli* in accordance with 9 CFR 310.25. Written procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. (b) (4)

[REDACTED] (Attachment 7). The laboratory will use an AOAC approved (b) (4) method for analysis of *E. coli*. Records of all test results shall be maintained in (b) (4)

(b) (4) generic *E. coli* cfu will be considered defective and in that event, the following actions taken:

- 1) (b) (4)



2) (b) (4)

All data generated under this project will be reviewed to determine whether the (b) (4)

(e) Agency Sampling

USDA-FSIS will continue to conduct pathogenic Shiga toxin-producing *Escherichia coli* and *Salmonella* verification sampling per current sampling tasks (i.e., MT43, MT60, MT64). It is understood that FSIS Inspection Program Personnel (IPP) will verify procedures outlined in the waiver protocol are followed. This includes verification that effective implementation of alternative procedures for waived regulations is occurring in a manner consistent with the application and as supported by validation documents.

(f) Access and Maintenance of Records.

USDA-FSIS inspection program personnel shall have access to any records, including laboratory results, necessary to document control. On a weekly basis, we will permit USDA-FSIS access to all data generated under the testing described above. On a monthly basis, we will submit intervention CCP monitoring data to USDA-FSIS headquarters via mailbox@fsis.usda.gov in accordance with the template provided such that USDA-FSIS can analyze the data of the from the waiver.

Records generated under the above described inspection program will be maintained in the same manner and for the same duration as HACCP records, as specified in 9 CFR §417.5. However, since the data generated under this waiver constitutes trade secret and/or confidential commercial information and are being voluntarily provided to the government as part of this waiver protocol (the data and other information generated under this project), FSIS acknowledges that such data and documents are exempt from public disclosure and will not be released by the Agency pursuant to the Freedom of Information Act.

(g) Termination

USDA-FSIS will be provided with 30 days prior written notice before Tyson Fresh Meats facilities terminate participation in the project. In the event of termination, all data generated under the project, other than the micro sampling data, will be treated as confidential research data by Tyson Fresh Meats.

(h) Principal Contacts

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(i) **Attachments**

Attachment 1: Post Mortem Sorting & Identification SOP and Disposition Log

Attachment 2: Post Mortem Training Program Link - [Pre-sortation Training Modules](#)

Attachment 3: Slaughter HACCP Program (Est. 278) that includes:

- a) Process Category Description,
- b) Flow Charts,
- c) Hazard Analysis
- d) Master Sheet
- e) CCP Monitoring Forms

Attachment 4: Raw Not Ground Variety Meats HACCP Program (Est. 278) that includes:

- a) Process Category Description,
- b) Flow Charts,
- c) Hazard Analysis
- d) Master Sheet
- e) CCP Monitoring Forms

Attachment 5: Carcass Sanitary Intelligence (CSI) Sanitary Dressing Pre-requisite Program and (a)Monitoring Forms (Est. 278)

Attachment 6: In Process Contamination (IPC) Pre-requisite Program and (a)Monitoring Forms (Est. 278)

Attachment 7: Generic E. coli Carcass Sampling SOP dated 12/13/16

Attachment 8: Worker Safety Attestation

Attachment 9: Animal Welfare Attestation

