LETTER OF DEFERRAL

Dear Mr. DeVries:

This letter serves as official notification of the Food Safety and Inspection Service’s (FSIS) decision to place the Notice of Intended Enforcement (NOIE), dated November 4, 2020, into deferral. This action is based on the review, analysis, and acceptance of your proposed corrective actions and preventive measures submitted to the FSIS Chicago District Office on November 6 and November 9, 2020.

Background

On November 4, 2020, Deputy District Manager Dr. Tamara Davis verbally notified you of the Food Safety and Inspection Service’s (FSIS) intent to withhold the marks of inspection and suspend the assignment of inspectors from your slaughter process at Caledonia Packing LLC, establishment M46200, located at 3892 92nd St SE in Caledonia, Michigan. This action was based on your establishment’s failure to effectively implement humane methods of slaughtering and handling animals in a manner that complies with the regulatory requirements prescribed by the Federal Meat Inspection Act (FMIA) and the Humane Methods of Slaughter Act (HMSA). Your establishment was observed to be in violation of Title 9 of the Code of Federal Regulations (9 CFR), Sections 313.16(a)(1) and 313.16(b)(1)(iii). The Rules of Practice, 9 CFR 500.3(b), specify that FSIS may issue a suspension without providing prior notification if an establishment is handling or slaughtering animals inhumanely.

Because your establishment maintains a written systematic approach for the humane handling of livestock consistent with the guidelines for robustness and you were implementing the program as written, regulatory discretion was exercised and the decision was to issue an NOIE in lieu of a suspension.

Within the NOIE, the FSIS Chicago District Office requested that you submit a written response within three (3) working days from the date of your receipt of the NOIE with corrective actions to address the following:

1. Identify the cause of the humane handling incident.
2. Describe the corrective actions you will implement to eliminate the cause and prevent recurrence.
3. Describe the verification monitoring you will conduct to ensure the corrective actions are effective.
4. Provide any supporting documentation associated with your corrective actions.

**Corrective Actions**

On November 6, 2020, the FSIS Chicago District Office received your written response. After a review and analysis, the District Veterinary Medical Specialist (DVMS) contacted you via telephone to discuss the proposed activities and request clarification. You submitted a revised response to address those issues on November 9, 2020.

You identified the cause of the incident was that the sow confined to the knock box moved and was able to leverage the rear entry gate, opening it and escaping restraint. To restore and maintain regulatory compliance with the requirements of 9 CFR 313.16(a)(1) and 9 CFR 313.16(b)(1)(iii) you proposed the following corrective actions:

- To limit the free movement of sows and boars, the facility has installed a latch on the rear restraint gate to prevent future sows and boars from opening the restraint (Attachment A). This latch will be used on all sows and boars within the knocking box.
- To ensure all stunning employees understand the new practice, the facility held a meeting that detailed the new procedure (Attachment B).
- You have also conducted a full reassessment of your robust systematic animal handling plan where you found it prudent to include this measure within your plan (Attachment C).
- To verify the effectiveness of your corrective actions, an audit will be conducted on 100% of all sows and boars knocked per production day for the next consecutive 30 days. If after the 30-day period any corrective action failures occur, the 30-day verification procedure will be reinstated.
- Audit scores will be documented on the facility’s "Latch Audit" (Attachment D).
- If at any time during these audits the proposed corrective actions are found to be ineffective, the facility will immediately stop knocking and provide corrective actions.

You provided each of the referenced documents, Attachments A through D, for review.

The FSIS Chicago District Office has concluded these proposed measures, provided they are successfully implemented, will serve to adequately address the regulatory issues identified within the NOIE.

**Summary and Conclusion**

This letter serves as written notification that FSIS is deferring the decision to suspend the assignment of inspectors from the slaughter process at your establishment. The deferral of this decision will remain in effect until your proposed corrective actions are demonstrated to have been successfully implemented on a consistent and continuous basis. The corrective actions you proposed will be subject to verification by FSIS inspection program personnel (IPP) to ensure the
implementation is effective ensure no recurrence of events related to your establishment’s obligation for compliance with the FMIA, HMSA, and all applicable FSIS regulations.

FSIS is committed to monitoring establishments’ operations to verify compliance with the regulatory requirements. To assist in those verification activities, FSIS has developed a Verification Plan Report (VPR) based on your proposed corrective actions. The VPR will be completed by FSIS IPP during the deferral period as a means to document the implementation of your corrective actions in conjunction with the conditions of this deferral. The VPR identifies specific elements of your corrective actions and the associated regulatory requirements. These will be subject to verification until FSIS has made the determination that your establishment has effectively implemented these corrective actions. Additionally, during the deferral period, Humane Handling Verification Visits (HHVV) will be conducted at 30-day intervals to assess your progress in implementing the corrective actions as proposed. FSIS verification includes the expectation that you meet any time associated commitments identified within your proposal. Should your establishment fail to operate in accordance with these commitments or fail to comply with the regulatory requirements, FSIS will take immediate and appropriate regulatory control actions.

If you have questions regarding this matter, you may contact [Redacted], at this office at (630) 620-7474 or fax at (630) 620-7599.

Sincerely,

DONALD FICKEY

Dr. Donald B. Fickey
District Manager
FSIS Chicago District