



November 5, 2020

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Mr. Mike DeVries, Owner
Caledonia Packing LLC
Est. M46200
3892 92nd St SE
Caledonia, MI 49316

REVISED NOTICE OF INTENDED ENFORCEMENT

Dear Mr. DeVries:

This letter is being reissued due to the incorrect reference to a .410-gauge shotgun being used to stun the animal instead of the correct 20-gauge shotgun. This letter confirms verbal notification provided to you by Dr. Tamara Davis, Deputy District Manager, on November 4, 2020, at approximately 1250 hours EST, 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 Street SE in Caledonia, Michigan. This action is 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 is 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.

Background and Authority

The Federal Meat Inspection Act 21 U.S.C. 603 Sec. 3 (b) states, in part, "*for the purpose of preventing the inhumane slaughtering of livestock, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of the method by which cattle, sheep, swine, goats, horses, mules, or other equines are slaughtered and handled in connection with slaughter in the slaughtering establishments inspected under this Act. The Secretary may refuse to provide inspection to a new slaughtering establishment or may cause inspection to be temporarily suspended at a slaughtering establishment if the Secretary finds that any cattle, sheep, swine, goats, horses, mules, or other equines have been slaughtered or handled in connection with slaughter at such establishment by any method not in accordance with Sections 1901 to 1906 of Title 7 until the establishment furnishes assurances satisfactory to the Secretary that all slaughtering and handling in connection with slaughter of livestock shall be in accordance with such a method.*" In addition, under prohibited acts 21 U.S.C. 610 sec 10 (b), "*No person, establishment or corporation shall, with the respect to any cattle, sheep, swine, goats, horses, mules, and other equines, or any carcasses, parts of carcasses, meat or meat food products of any such animals slaughter or handle in connection with slaughter any such animals in any manner not in accordance with sections 1901 to 1906 of Title 7.*"

The Humane Methods of Slaughter Act 7 USC 1901 states, *“The Congress finds that the use of humane methods in the slaughter of livestock prevents needless suffering; results in safer and better working conditions for persons engaged in the slaughtering industry; brings about improvement of products and economies in slaughtering operations; and produces other benefits for producers, processors, and consumers which tend to expedite an orderly flow of livestock and livestock products in interstate and foreign commerce. It is the policy of the United States that the slaughtering of livestock and the handling of livestock in connection with slaughter shall be carried out only by humane methods.”*

The Humane Methods of Slaughter Act 7 USC 1902 states, *“No method of slaughtering or handling in connection with slaughtering shall be deemed to comply with the public policy of the United States unless it is humane.”* When an egregious situation exists, FSIS can refuse to render inspection and indefinitely withdraw inspection from an establishment provided the establishment is afforded the right to an administrative hearing.

Under the authority of the above Acts, FSIS has prescribed rules and regulations for establishments producing meat and poultry products to include the humane slaughter of livestock as required by 9 CFR 313, and other matters. FSIS has also developed Rules of Practice regarding enforcement, which can be found in 9 CFR 500. The Rules of Practice describe the types of enforcement actions that FSIS may take to include a withholding action and/or suspension, with or without prior notification, and for filing a complaint to withdraw a Grant of Federal Inspection.

Findings/Basis for Action

On November 4, 2020, at approximately 1118 hours EST, the FSIS Consumer Safety Inspector (CSI) was performing verification observations for stunning effectivity and described the following. A large sow was confined to the knock box. An employee attempted to stun the sow using a 20-gauge shotgun with slug ammunition. The CSI proceeded to the safe area and heard the firearm discharge followed by the sow continuously vocalizing. The CSI observed the employee wielding the shotgun position to place a second corrective action shot but he could not accurately do so and did not discharge the firearm. During this time, the rear gate of the knock box had lifted open and the animal fled the knock box by backing down the kill chute alleyway. The establishment employee set the firearm down, retrieved an electric prod, and proceeded to drive the sow back into the knock box from the drive alley. The sow was driven back into the knock box and the rear entry door was closed. The employee then retrieved the firearm and effectively stunned the sow with the second shot from the shotgun. Post-mortem examination revealed two holes in the head of the sow, one in the poll area and the other in the front. Further dissection of the head revealed a 20-gauge slug lodged in the head in the poll area, missing the cranial cavity and brain. The shot located in the front of the head entered the cranial cavity. The failure to maintain adequate restraint resulted in the inability to immediately administer effective corrective actions, which led to the prolonged discomfort and excitement of the animal as described.

You were informed that the slaughter process was under regulatory control and U.S. Reject Tag No. B38093518 was applied to the knock box. The occurrence of this inhumane handling incident constitutes an egregious violation of the humane handling requirements and is a violation of 21 U.S.C. 603, Section 3 (b) of the FMIA, and Sections 7 U.S.C. 1901 and 1902 of the HMSA of 1978. The incident as described is noncompliant with the regulatory requirements of 9 CFR 313.16(a)(1) which states, *“The firearms shall be employed in the delivery of a bullet or projectile into the animal in accordance with this section so as to produce immediate unconsciousness in the animal by a single shot before it is shackled, hoisted, thrown, cast, or cut. The animal shall be shot in such a manner that they will be rendered unconscious with a minimum of excitement and discomfort,”* and 9 CFR 313.16(b)(1)(iii) which specifies, *“The stunning area shall be so designed and constructed as to limit the free movements of animals sufficiently to allow the operator to locate the stunning blow with a high degree of accuracy.”*

Summary and Conclusion

On September 9, 2004, FSIS published "Humane Handling and Slaughter Requirements and the Merits of a Systematic Approach to Meet Such Requirements" in the Federal Register Notice 54 Fed. Reg. 54625. On August 15, 2011, FSIS released FSIS Directive 6900.2 Revision 2, entitled, "Humane Handling and Slaughter of Livestock." Additionally, on October 23, 2013, FSIS introduced new guidance, titled "FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock." Within the guidance material is information intended to better ensure the humane treatment of livestock presented for slaughter. The guidance material provides a set of practices designed to minimize excitement, discomfort, and accidental injury regarding the humane handling of livestock to include the four components of a robust systematic approach to humane handling.

In cases where an egregious animal handling incident is observed by FSIS inspection program personnel (IPP), the Agency provides for regulatory discretion in the decision regarding the type of enforcement action issued, provided an establishment maintains and implements a written systematic approach that meets the criteria for robustness.

Your establishment is currently operating under an animal handling and welfare program that provides for how your establishment will respond if an event of this nature occurs. The decision to issue a Notice of Intended Enforcement (NOIE) in lieu of a Notice of Suspension (NOS) is based on your implementation of a written systematic approach for the humane handling of livestock in a manner consistent with the Agency expectations for consideration of a robust systematic approach.

Based on the evaluation of this plan, your response in accordance with your animal handling program is expected to effectively address the regulatory issues identified within this letter. Before proceeding with any enforcement action, we are affording you the opportunity to demonstrate why a determination should not be made that your slaughter process is inadequate or to demonstrate that you have achieved regulatory compliance.

Please provide this office with a written response to this NOIE within three (3) working days from the date of your receipt of this letter. We will determine if any further actions are necessary based on your response. The corrective actions and preventive measures in your response should address the following:

1. Identify the reason(s) why the events described occurred.
2. Describe the specific action(s) that will be implemented to eliminate the cause of the incident and prevent future recurrences.
3. Describe the future monitoring activity or activities that your establishment will employ to ensure the actions implemented are effective.
4. Provide any supporting documentation and records maintained and associated with your proposed corrective actions and preventive measures.

Please note, these proposed corrective actions and preventive measures should be specific in detail and include any time/date related commitments for completion.

You have the right to appeal this matter. Your appeal should be addressed to the following:

Paul V. Wolseley
Executive Associate for Regulatory Operations
Office of Field Operations
Food Safety and Inspection Service, USDA
1400 Independence Ave. SW

Room 3159 South Building
Washington, DC 20250
Office: (202) 708-9506
Cell: (630) 544-9805
paul.wolseley@usda.gov

In addition, you may also request a hearing regarding this determination pursuant to FSIS' Rules of Practice (9 CFR Part 500). The Rules of Practice were published in the Federal Register, Vol. 64, No. 228, on November 29, 1999. As specified in Section 500.5(d), should you request a hearing, FSIS will file a complaint that will include a request for an expedited hearing. If you wish to request a hearing regarding this determination, you should contact:

Scott C. Safian, Branch Chief
Enforcement Operations Branch
Office of Investigation, Enforcement and Audit
Food Safety and Inspection Service
United States Department of Agriculture
Stop Code 3753, PP3, Cubicle 9-235-A
1400 Independence Ave. SW
Washington, DC 20250
Fax: (202) 245-5097

If you have questions regarding this matter, you may contact (b) (6)

(b) (6)

or you may

contact this office at (630) 620-7474 or by fax at (630) 620-7599.

Sincerely,



Dr. Donald Fickey
District Manager
FSIS Chicago District