



May 8, 2020

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Mr. Dave Dorley, Owner
Keystone Meats Inc.
Est. M15826
3585 Harding Hwy
Lima, Ohio 45804

NOTICE OF SUSPENSION HELD IN ABEYANCE

Dear Mr. Dorley:

This letter confirms verbal notification provided to Mr. Pete Dorley, President, by Dr. Karnail Mudahar, Deputy District Manager, on May 8, 2020, of the Food Safety and Inspection Service's (FSIS) decision to place the Notice of Suspension (NOS) dated May 8, 2020, into abeyance. 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 May 8, 2020.

Background

On May 8, 2020, Mr. Mike Biederman, Plant Manager, was notified of the FSIS decision to withhold the marks of inspection and suspend the assignment of inspectors from your slaughter process, Establishment M15826, Keystone Meats Inc., located at 3583 Harding Hwy in Lima, Ohio. 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 requirements prescribed by the Federal Meat Inspection Act (FMIA) and the Humane Methods of Slaughter Act of 1978 (HMSA). Your establishment was in violation of Title 9 of the Code of Federal Regulations (9 CFR), Sections 313.15(a)(1) and 313.15(b)(1)(iv). The Rules of Practice, 9 CFR 500.3(b), specify that FSIS may issue a suspension without providing prior notification if an establishment is observed to be handling or slaughtering animals inhumanely. You were provided a written copy of the NOS.

Within the NOS, the FSIS Chicago District Office requested that you submit a written response with corrective actions and preventive measures that, at a minimum, address the following:

1. Identify the specific 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 specific 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.

Corrective Actions

On May 8, 2020, your establishment submitted a written response describing the corrective actions proposed as a means to restore and maintain regulatory compliance as required. The response identified that the cause of the incident was an untrained employee, on his first attempt at stunning, made two unsuccessful attempts to stun a dairy cow. Your establishment submitted an initial response for review, and the District Veterinary Medical Specialist (DVMS) initiated a follow up phone call to discuss additional details and clarifications for those corrective actions. Your establishment provided a revised response, and again the DVMS followed up with a phone call to clarify aspects of that response. Your establishment then submitted another revised response in which you proposed the following corrective actions to restore and maintain regulatory compliance as required:

1. The inexperienced employee was immediately replaced by an experienced employee who will be performing stunning until a training program is developed and implemented.
2. Only experienced people will stun livestock.
3. Verification monitoring for stunning will be conducted for 100% of the remaining animals for today's slaughter, and the results will be documented to include the identification of the animal, if the first attempt was successful, if the animal remained unconscious, and if a corrective action was required, and the date.
4. Verification monitoring for stunning after today will be documented using the same criteria listed above for at least 20 animals each slaughter day during the abeyance period.
5. You provided the verification monitoring document for review.
6. As part of the future corrective actions, a training program for stunning will be developed and submitted to FSIS for review no later than August 28, 2020.
7. The new stunning operator will not be allowed to knock cattle until he has completed the approved training program.
8. Documentation of training will be created and maintained for every employee who knocks cattle.
9. No employee will be allowed to knock cattle who has not been trained, and this will be documented.

Please note, once the training program is submitted for review, the training program as well as the implementation will be subject to FSIS review, acceptance, and verification as part of the abeyance.

After a review and analysis of your proposed corrective actions, the FSIS Chicago District Office has concluded that these corrective actions, provided they are successfully implemented, will serve to adequately address the regulatory issues identified within the NOS.

Summary and Conclusion

This letter serves as written notification that FSIS is placing the suspension at your establishment into abeyance. The abeyance will remain in effect until such time as you have demonstrated successful and effective implementation of the proposed corrective actions. The implementation of the corrective actions will be subject to verification by FSIS inspection program personnel (IPP) to ensure no repetition of noncompliance related to your responsibilities regarding the applicable statutes and regulations.

FSIS is committed to monitoring establishments' operations to verify that they are fully complying with all regulatory requirements. To assist in those verification activities during the abeyance period, FSIS has developed a Verification Plan Report (VPR) based on your proposed corrective actions. The VPR will be completed by FSIS IPP as a means to verify and document regulatory compliance in conjunction with the conditions of this abeyance. The VPR identifies specific elements of your corrective actions and the associated regulatory requirements. These will be subject to verification until FSIS has concluded that your establishment has successfully implemented these corrective actions as proposed. FSIS verification includes the expectation that you meet any time associated commitments identified within your corrective actions. Should your establishment fail to operate in accordance with these commitments or fail to comply with the regulatory requirements, FSIS will take appropriate and immediate regulatory control actions.

You are reminded that as an operator of a federally inspected facility, you are expected to fully comply with all FSIS regulations and to take appropriate corrective actions to prevent the inhumane treatment and slaughter of livestock. The Humane Methods of Slaughter Act of 1978 (Section 1901, 1902, and 1906) states that the slaughtering and handling of livestock are to be carried out only by humane methods. 9 CFR 313 contains the FSIS regulatory requirements that were promulgated based on the HMSA and the FMIA. It is fully expected that you comply with the HMSA, FMIA, and the regulatory requirements of Part 313, and that you carry out each of the corrective and preventive actions you proposed in response to the egregious incident. Failure to comply could result in the reinstatement of suspension at your facility or other appropriate administrative or legal actions. We urge your company's cooperation and voluntary compliance.

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,

Digitally signed by KARNAIL
MUDAHAR
Date: 2020.05.08 13:28:05 -05'00'
KARNAIL MUDAHAR
Dr. Karnail Mudahar
Acting District Manager
Chicago District