



August 7, 2020

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

NOTICE OF REINSTATEMENT OF SUSPENSION HELD IN ABEYANCE

Dear Mr. Dorley:

This letter confirms verbal notification provided to Mr. Pete Dorley, President, on August 7, 2020, by Dr. Karnail Mudahar, Deputy District Manager, of the Food Safety and Inspection Service's (FSIS) decision to place the Notice of Reinstatement of Suspension (NROS) dated August 7, 2020, into abeyance. This action is based on the review, analysis, and acceptance of your collective proposed corrective actions and preventive measures submitted to the FSIS Chicago District Office on August 7, 2020.

Background

On August 7, 2020, you were notified of FSIS' decision to withhold the marks of inspection and suspend the assignment of inspectors from your slaughter process at Keystone Meats Inc., establishment M15826, located at 3585 Harding Hwy in Lima, Ohio, for 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), Humane Methods of Slaughter Act (HMSA), and Title 9 of the Code of Federal Regulations (9 CFR) section 313.15(a)(3). 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 you were operating within the abeyance period of a previous Notice of Suspension (NOS) dated May 8, 2020, which was placed into abeyance that same day, the suspension was reinstated.

You were provided a written copy of the NROS requesting that you submit a written response with corrective actions and preventive measures that, at a minimum, specifically 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 August 7, 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 the stunning operator not observing the stunned animal long enough to ensure that it remained unconscious and instead left the area to bring another animal into the knock box. Your establishment submitted an initial response for review, and after a review and analysis of your proposed corrective actions, the FSIS Chicago

District concluded the response lacked sufficient detail and requested additional information. You were provided an inadequate response letter specifying the additional information. Your establishment then submitted a revised 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 then submitted an amended response in which you proposed the following corrective actions to restore and maintain regulatory compliance as required:

1. The stunning operator will be instructed on a new procedure before operations resume. The new procedure is that the stunning operator is required to monitor the animal continuously until sticking and bleeding is initiated. The instruction of this new procedure to the stunning operator will be documented on attached form signed by the operators to verify the review is done before operations resume. A form documenting completed training was provided.
2. The new procedure will be incorporated into our SOP "Training for Stunning of Cattle" also.
3. The entire training packet will be reviewed with the stunning operator. Documentation of this review will take place on attached form. This training packet includes:
 - a. Signs of consciousness that the operators need to watch for; namely vocalization, eye blinks, eye reflexes in response to touch, rhythmic breathing, curled tongue, remain standing, or righting reflex.
 - b. Appropriate corrective actions if any sign of consciousness is observed, namely immediately stunning the animal a second time with a stunner or firearm.
 - c. Evaluation of shot placement will be done on at least 10 cattle each kill day until end of abeyance period. This will be documented on the attached log sheet.
4. (b) (6) and (b) (6) roles will be filled by (b) (6) and (b) (6), both of whom are experienced in animal handling and stunning. They will both be trained on new procedure before operations resume. A form documenting completed training for both individuals was provided.
5. Immediate response is that the supervisor will monitor experienced employee continuously today. Documentation to be used to ensure stunning operator monitors animals continuously until sticking and bleeding was provided. This form will be used to document the monitoring of stunning of at least 10 cattle each kill day for the entire abeyance period.
6. Documentation of training will be created and maintained for every employee who knocks cattle. No employee will be allowed to knock cattle who has not been trained, and this will be documented.
7. You will create the revisions to your training program with associated documentation and verification and submit them to the Chicago District Office for review and approval by November 6, 2020.

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

Summary and Conclusion

This letter serves as written notification that FSIS is placing the suspension of the assignment of inspection program personnel (IPP) 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 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), or you may contact this office at (630) 620-7474 or by fax at (630) 620-7599.

Sincerely,

KARNAIL
MUDAHAR

Digitally signed by KARNAIL
MUDAHAR
Date 2020.08.07 20:58:42 -05'00'

Dr. Karnail Mudahar
Acting District Manager
Chicago District