3/18/2023

HyLife Foods Windom LLC
EST. #45856
2850 Hwy. 60 East
Windom, MN  56101

Attention: (b) (6) Est. Administrator

NOTICE OF REINSTATEMENT OF SUSPENSION

This letter serves as official notification by the Food Safety and Inspection Service (FSIS) of our decision to withhold the federal marks of inspection and suspend the assignment of Inspection Program Personnel (IPP) at HyLife Foods Windom, LLC, EST.#45856, located at 2850 Hwy. 60 East, Windom, MN., 56101. This letter follows verbal notification of the reinstatement of suspension action, provided by (b) (6) SPHV, to (b) (6) at approximately 12:15 PM on March 18, 2023. This action includes your Slaughter Hazard Analysis Critical Control Point (HACCP) processes employed at your establishment.

The decision to institute this enforcement action is in accordance with Title 9 of the Code of Federal Regulations (CFR), Rules of Practice 500.3(b), based on the determination that your establishment did not handle or slaughter animals humanely. The evidence demonstrates failure to comply with the Federal Meat Inspection Act (FMIA) (21 U.S.C. 603), the Humane Methods of Slaughter Act (HMSA) (7 U.S.C. 1901 et seq.), and the regulatory requirements (9 CFR Part 313).

Background/Authority

The FMIA (21 USC 601 et seq.) provides it is essential to the public interest that the health and welfare of consumers be protected, by assuring meat products distributed to them are wholesome, not adulterated, and properly marked, and labeled. The Act gives FSIS the authority, as designated by the Secretary of Agriculture, to prescribe rules and regulations describing sanitation requirements for inspected establishments and provide FSIS program personnel the authority to refuse to allow meat/meat food products to be marked, labeled, stamped, or tagged as inspected and passed, to prevent the entry of adulterated products into commerce. Furthermore, the FMIA provides FSIS the authority to appoint inspectors to examine and inspect the method by which livestock are slaughtered and handled at slaughtering establishments.

The HMSA provides that Congress finds that the use of humane methods in the slaughter of livestock prevents needless suffering; results in safer and better working conditions; and promotes the welfare of the livestock.
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 therefore declared to be 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.

Under the authority of the Acts, FSIS has prescribed rules and regulations required for establishments slaughtering and handling livestock, as required by 9 CFR Part 313. FSIS has also developed the Rules of Practice regarding administrative enforcement, 9 CFR Part 500. The Rules of Practice describe the types of enforcement actions that FSIS may take and include procedures for taking a withholding action and/or suspension, with or without prior notification, and for filing a complaint to withdraw a grant of inspection. Specifically, 9 CFR 500.3(b) states that FSIS may impose a suspension without providing prior notification due to handling or slaughtering of animals inhumanely.

Findings/Basis for Action

At approximately 1122 hours on 03/18/2023 while FSIS personnel were in the barn verifying HATS Category VIII Stunning Effectiveness as part of a verification plan for Notice of Suspension dated 01/16/2023, an establishment employee was observed attempting to stun a hog by the resale pen. As the captive bolt stunner fired, the hog vocalized making a high-pitched squeal, the conscious hog was then observed moving forward on its feet behind the sort boards into the corner by the suspect pen, then went down in sternal recumbency. The employee immediately administered a second stun attempt with the other loaded hand-held captive bolt stunner. The hog righted itself, standing up, and made a conscious effort to walk forward with coordinated, purposeful movement, stumbling after a few steps. It turned around and went down on its front legs, still standing on its hind legs. Blood was observed running from the captive bolt wounds on its head. One of the employees immediately went to grab more charges from the captive bolt boxes nearby. One of the handheld captive bolt stunners was then immediately reloaded and the captive bolt stunner was readministered rendering the hog unconscious. Three captive bolt wounds were observed on this hog’s head. One was just to the left of the midline on the forehead approximately 2.5 cm dorsal to the level of the eyes. Another was just dorsal to this wound approximately 3 cm dorsal to the level of the eyes. The third wound was approximately 1.5 cm to the right of the midline and approximately 3 cm dorsal to the level of the eyes. This is noncompliant with 9 CFR 313.15(a)(1) in that the establishment failed to render this animal unconscious on the first attempt. Immediate regulatory control action was taken by verbally informing Animal Welfare Coordinator [redacted] to immediately stop using the captive bolt stunners and to bring them to the scale office, stopping production. She was informed of the noncompliance and that the district office would be contacted. After contacting the district office, Quality Assurance Manager [redacted] was also notified of the noncompliance and that the CO2 stunner would be tagged. The CO2 stunner was then tagged with U.S. Rejected tag NO. B-46 568472. After further discussion with the district office, [redacted] was verbally notified of the reinstatement of suspension and that a noncompliance record would be issued. [redacted] was also notified of the reinstatement of suspension and that a noncompliance record would be issued. This noncompliance record is being associated with a similar
noncompliance that was documented on 01/16/2023 (ref. NR#OBD3515014716N). The establishment failed to implement the corrective actions, or the measures implemented were inadequate to prevent recurrence. Continued failure to meet regulatory requirements may lead to further enforcement action as described in 9 CFR 500.4.

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 (69 FR 54625). On September 24, 2020, FSIS released FSIS Directive 6900.2 Revision 3, 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.

When an establishment maintains a robust humane handling program, FSIS can exercise regulatory discretion when an inhumane handling or slaughter incident is observed. You do not currently maintain a written humane handing program for consideration.

Summary and Conclusion

Provisions of the FMIA outline FSIS’ ability to refuse to render inspection and indefinitely withdraw inspection from an establishment, provided the establishment is afforded the right to an administrative hearing, when conditions exist where the slaughter and/or handling of livestock was not by a method in accordance with the Act(s). Evidence demonstrates your failure to meet regulatory requirements addressed in 9 CFR 313.15(a)(1), constituting a violation of the humane slaughter requirements, and supporting the conclusion that your handling of livestock violated the provisions of the FMIA and HMSA.

Please provide a written response, inclusive of written corrective action and preventative measures, by addressing the following:

- Evaluate and identify the nature, cause of the incident.
- Describe the specific actions taken to eliminate the cause of the incident and prevent future recurrences.
- Describe specific monitoring activities planned to ensure future compliance.
- Provide any supporting documentation and records maintained and/or associated with the proposed corrective actions and preventative measures.

A determination of further administrative action will be made upon receipt and review of your submitted corrective actions and preventative measures. You are reminded that, as an operator of a federally inspected establishment, you are expected to comply with FSIS regulations and to take appropriate corrective actions to prevent the production of or adulterated products at your establishment. Please be advised that your failure to respond adequately to these issues may result in our initiating action to withdraw inspection from your establishment.
Appeal and Hearing Rights

You have the right to appeal this matter and can do so by contacting:

Sherri N. Johnson,
Executive Associate for Regulatory Operations
Office of Field Operations
Food Safety and Inspection Service
United States Department of Agriculture
SB, Room 1330A
1400 Independence Avenue, SW
Washington, DC 20250
Email: sherri.johnson@usda.gov
Phone: 202-379-6196

Pursuant to 9 CFR 500.5(d), you may also request a hearing regarding this determination. 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, please contact:

Scott C. Safian, Director
Enforcement Operations Staff (EOS)
Office of Investigation, Enforcement and Audit (OIEA)
Food Safety and Inspection Service
United States Department of Agriculture
Stop Code 3753, SB - Room 2148
1400 Independence Avenue, SW
Washington, DC 20250
Telephone: (202) 418-8872
Facsimile: (202) 245-5097
E-mail: AEBCorrespondence@usda.gov

If you have any questions, please contact the Des Moines District Office at 515-727-8960, District Veterinary Medical Specialist (DVMS), at (b) (6), or DVMS, at (b) (6).  

Sincerely,

RANDALL KUMPOST
Digitally signed by RANDALL KUMPOST
Date: 2023.03.18
17:28:57 -05'00'

Dawn Sprouls
District Manager
cc: Sherri Johnson, EARO
     Dawn Sprouls, DM
     Shaun Smith, OIEA Regional Director
     Mark Johnson, DDM
     Todd Gerwig, DDM
     Jeff Jacobsen, DDM
     (b) (6) , SeIAO
     (b) (6) , DCS
     (b) (6) , DVMS
     (b) (6) , FLS
     IIC at EST. 45856
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