

March 18, 2025

Electronically sent on March 18, 2025

Big Sky Processing LLC., M/V46090 181 Cut Above Loop Moore, MT 59464 bigskyprocessingllc@gmail.com cattlesale@wispwest.net (406) 220-3329

Attention: Nicole Wines, Owner

REINSTATEMENT OF SUSPENSION (ROS)

This letter confirms the verbal notification provided to your establishment, Big Sky Processing, LLC., Establishment M/V46090, located in Moore, MT on Tuesday, March 18, 2025, by the Food Safety Inspection Service (FSIS) Denver District, of the reinstatement of suspension (ROS) of the assignment of inspectors and the withholding of the marks of inspection at your establishment for slaughter operations. Ms. Jenifer Monteverde, Deputy District Manager, notified Nicole Wines, plant owner and Kelly Richardson, plant manager, of the suspension action at approximately 3:30 PM (MT) on 03/18/2025. This action was initiated in accordance with Title 21 of the United States Code (USC), Section 603(b) and Title 9 of the Code of Federal Regulations (CFR) Part 500.3(b) (Rules of Practice).

Background/Authority

FSIS is the agency in the U.S. Department of Agriculture responsible for protecting the public's health by ensuring the nation's supply of meat, poultry, and processed egg products for sale and distribution in commerce is safe, unadulterated, wholesome, and correctly labeled and packaged. FSIS administers and enforces, among other laws, the FMIA, HMSA, and the statutes' implementing regulations. FSIS has prescribed rules and regulations required for establishments producing meat/meat food products, including requirements pertaining to humane handling and slaughtering of livestock (9 CFR Part 313) and other matters. FSIS has also developed the Rules of Practice regarding enforcement (9 CFR Part 500). The Rules of Practice describe the types of enforcement action 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 Federal Grant of Inspection.

Should FSIS personnel document serious or repetitive food safety, sanitation, humane handling, slaughter, or other violations, FSIS may take enforcement action under 9 CFR Part 500.

Links to the Acts and the Rules of Practice are enclosed for your information and review.

FMIA: https://www.fsis.usda.gov/policy/food-safety-acts/federal-meat-inspection-act
HMSA: https://www.fsis.usda.gov/policy/food-safety-acts/humane-methods-slaughter-act
FSIS Rules of Practice: https://www.ecfr.gov/current/title-9/chapter-III/subchapter-E/part-500

Findings/Basis for Action

On Tuesday, March 18, 2025, the FSIS Consumer Safety Inspector (CSI) documented in a Noncompliance Record (NR) the following event at Est. M/V46090:

"On Tuesday March 18, 2025, at approximately 1419 hours, I, the CSI, was present on the slaughter floor, preparing to conduct post-mortem inspection on a carcass, when I observed the stun operator exit the building to the stun box alongside another employee to stun a single pig within the stun box. The stun operator, from inside the stun box, utilized a .410 shotgun loaded with birdshot and applied what was thought to be an effective stun to the pig on the first attempt as the pig dropped to the floor. Meanwhile, another employee opened the garage door to allow the carcass to enter the slaughter room floor. As the plant employee proceeded to stick the animal, as there was a slow trickle of blood from the stick, I observed the pig emit a loud squeal and blink its eyes multiple times. I also observed that the animal was breathing rhythmically. I informed the employee that the pig was still alive and required another stun. The plant employee retrieved the readily available hand-held captive bolt device and applied a second stun attempt to the animal on the forehead. The plant employee remarked that the animal did not appear to be alive. As the plant employee attempted to finish the sticking process for bleeding, the animal squealed again. The employee approached me, asserting that the pig was indeed lifeless. However, when I looked back at the pig, I observed the pig standing on all four limbs, attempting to walk away, with its eyes open and making audible sounds while bleeding from the neck. The stun operator applied a third stun with the captive bolt rendering the animal insensible. I applied U.S. Reject tag B-45150101 to the stun box and verbally notified the plant manager of the forthcoming noncompliance record.

Upon inspection of the dressed head, there was penetrating birdshot above the left eye, a penetrating captive bolt hole to the left of center on the forehead and a third penetrating captive bolt hole within the target zone.

The Denver District Management Team was notified through supervisory channels. This noncompliance is being associated with noncompliance record #CRP2318022220N-1 issued on 2/20/2025 for the same root cause. This establishment is operating within the abeyance period for an egregious humane handling event."

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 (69 FR 54625). Subsequently, on October 23, 2013, FSIS issued guidance, titled "FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock," to promote a systematic approach to achieve compliance with the FSIS requirements for the humane handling and slaughter of livestock.

The decision to reinstate the suspension of the assignment of inspectors at your establishment is based on your establishment's humane handling noncompliance history and the findings

described above, in which, M/V46090 handled or slaughtered livestock inhumanely, in violation of the FMIA 21 U.S.C. 603(b), HMSA 7 U.S.C. 1901 – 1902, and

- Title 9 CFR 313.15(a)(1) The captive bolt stunners shall be applied to the livestock in accordance with this section to produce immediate unconsciousness in the animals before they are shackled, hoisted, thrown, cast, or cut. The animals shall be stunned in such a manner that they will be rendered unconscious with a minimum of excitement and discomfort. and,
- Title 9 CFR 313.15(a)(3) Immediately after the stunning blow is delivered the animals shall be in a state of complete unconsciousness and remain in this condition throughout shackling, sticking and bleeding. and,
- Title 9 CFR 313.15(b)(1)(iii) 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. and,
- Title 9 CFR 313.16(a)(1) 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,
- Title 9 CFR 313.16(a)(3) Immediately after the firearm is discharged and the projectile is delivered, the animals shall be in a state of complete unconsciousness and remain in this condition throughout shackling, sticking and bleeding, and,
- Title 9 CFR 313.16(b)(1)(iii) The provisions contained in § 313.15(b)(1)(iii) with respect to the stunning area also apply to the shooting area.

In accordance with Title 9 CFR Part 500.3(b), FSIS is exercising its authority to withhold the marks of inspection and suspend inspection services for the Slaughter HACCP processes at M/V46090, effective immediately.

You were operating under the abeyance period for a Reinstatement of Suspension issued on February 24, 2025, whereby your employee needed multiple stunning attempts with a firearm to render a bovine unconscious. As your firm is not operating with a Robust Systematic Approach, regulatory discretion by the Denver District Office is not an option.

The suspension of the assignment of inspectors will remain in effect until such time as you provide the Denver District Office adequate written corrective actions and preventative measures to ensure that livestock at your establishment are handled and slaughtered humanely, and in accordance with the FMIA, the HMSA and 9 CFR 313 regulations.

These should include:

- A written description of the incident.
- The root cause of the incident.
- Your immediate corrective actions.
- Any training or retraining of employees you plan to provide, including materials you're planning to use.
- Any monitoring procedures, including any documentation records.

In accordance with Title 9 CFR 500.5(a)(5), you may appeal this action by contacting:

Karen Hunter
Executive Associate for Regulatory Operations
Office of Field Operations
Food Safety and Inspection Service
United States Department of Agriculture
1400 Independence Avenue, SW
Room 3160, South Building
Washington, DC 20250
Email: karen.hunter@usda.gov

Phone: (202) 499-0275

In accordance with Title 9 CFR Part 500.5 (d), you may request a hearing concerning this action by contacting:

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
Office: (202) 418-8872
Fax: (202) 245-5097

E-mail: EOSCorrespondence@usda.gov

If you have any questions regarding this matter, you may contact the Denver District Office at (303)236-9800.

Sincerely,

Digitally signed by ROBERT

ROBERT REEDER REEDER

Date: 2025.03.18 17:40:32 -06'00'

Dr. Robert Reeder District Manager USDA FSIS OFO Denver District Office Robert.Reeder@usda.gov

cc: FO/QER Est. File

> K. Hunter, EARO D. James, DDM

J. Monteverde, DDM

J. VanHook, DDM	
(b) (6), SPHV	
(b) (6)	, CSI
(b) (6)	DVMS
(b) (6)	, DVMO
(b) (6)	DVMO
(b) (6)	DVMO
(b) (6)	, SEIAO
(b) (6)	, SEIAO
S. Smith, RD/OIEA	