United States Department of Agriculture

Food Safety and
Inspection Service

Raleigh District Office

6020 Six Forks Road
Raleigh, NC. 27609
Voice: [redacted]
Fax: [redacted]

07/31/2024

Hand Delivered by EIAO on July 31, 2024
Electronically Submitted on July 31, 2024

Boar's Head Provisions, Co., Inc.,
Est. M12612
2230 Wyatts Mill Road P.O. Box 277
Jarratt, Virginia 23867
[redacted]

Revision of the NOTICE of SUSPENSION

Attention: [redacted], Plant Manager

This letter serves as written notification by the Food Safety and Inspection Service (FSIS) of our decision to withhold the federal marks of inspection and suspend the operations of Ready-to-Eat (RTE) products at Boar's Head Provisions, Co., Inc., Est. M12612, located at 2230 Wyatts Mill Road P.O. Box 277 Jarratt, Virginia 23867. This letter follows verbal notification of the suspension action, provided by me to the establishment representatives at approximately 3:10 pm on Monday, July 29, 2024.

The decision to institute this enforcement action is in accordance with Title 9 of the Code Federal Regulations (CFR), Rules of Practice 500.3(a)(4), based on the determination that your establishment failed to maintain sanitary conditions, as required by 9 CFR 416 *et seq*., and 500.3(a)(1), based on the determination that your establishment produced and shipped adulterated product.

Background/Authority

The Federal Meat Inspection Act (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 and poultry 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 or poultry/poultry food products to be marked, labeled, stamped, or tagged as inspected and passed, to prevent the entry of products into commerce. This Act provides definitions for the term adulterated and further provide FSIS the authority to appoint inspectors to examine and inspect all carcasses, parts of carcasses and products as well as the sanitary conditions of facilities.

Under the delegated authorities of this Act, FSIS has prescribed rules and regulations required for establishments producing meat/meat food products and poultry/poultry food products, including the requirements pertaining to Sanitation Standard Operating Procedures (SSOP) and Sanitation Performance Standards (SPS) (9 CFR 416) and other matters. FSIS has also developed the Rules of Practice regarding enforcement (9 CFR 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. FSIS can refuse to render inspection and indefinitely withdraw inspection from an establishment, provided the establishment is afforded the right to an administrative hearing.

Findings/Basis for Action

This revised notice of suspension retains all the contents of the original notice of suspension that was issued on July 26, 2024, with the addition of the findings detailed below.

Your establishment defines *Listeria monocytogenes* (*Lm)* as low risk in the ready to eat (RTE) post-lethality exposed processing environment that includes post-chill, peeling (if applicable), refrigerated, splitting (if applicable) environment due to employee practices in the GMP Plan which reduce the likelihood of product recontamination, along with monitoring employees and environment through the SSOP plan. Your program further states that "*The risk is further reduced through an SSOP Plan conforming to Alternative 3 and Listeria sampling as required in 9 CFR 430 and Directive 10,240.4. Packaging Step."*

Your establishment produced product adulterated with *Lm* linked to an ongoing outbreak of *Lm*. As of July 30, 2024, this outbreak of *Lm* includes 34 ill people from 13 states; 33/33 (100%) of ill people with information available have been hospitalized and there are 2 reported deaths attributed to listeriosis. The Maryland Department of Health tested an unopened liverwurst product (Boar's Head Strassburger Brand Liverwurst, Sell By date 8/10/24, lot code J3 09:54) and the sample tested positive for *Lm*. On July 29, 2024, whole genome sequencing (WGS) was completed (IDs PNUSAL0022703, PNUSAL0022704, and PNUSAL0022702) and WGS data showed that the *Lm* isolated from the liverwurst sample is highly related to the *Lm* making people sick in this outbreak.

On July 24 and 25, 2024, Intensified Verification Testing (IVT) sampling was conducted, and one (1) sample, identified as non-food contact surface/environmental, tested positive for *Lm.* This sample was collected from the following location:

- Line 2: Non- Product Contact Surface Sponge, form # 103433961 confirmed positive for *Lm*, site description: Pallet Jack SH3 during the production of Beechwood Ham lot #9624.

Pallet Jack SH3 is used to move racks of product out of blast coolers to production lines in the processing room, as well as move product racks around the processing room. The processing room consists of one large open room. Processing lines 1 through 4 are located on the left side when standing with back to the coolers and Processing Lines 5 through 8 are located on the right side and used to process hot dogs and other small sausages. There are no barriers or walls that

separate the processing lines. Pallet jacks and product racks move between all processing lines and all blast coolers.

This positive *Lm* result on the pallet jack demonstrates *Lm* is present in the RTE post lethality processing environment and there are inadequate controls to prevent its spread throughout the RTE post lethality processing environment.

In addition, there is a risk of employees spreading *Lm* through the RTE post lethality processing environment. Although employees typically work on one line, when needed they may move between lines to help. Your establishment does not have a written plan to describe employee practices and use of personal protective equipment (PPE) when moving between lines. When EIAO discussed this with [redacted], the QA Manager, she stated verbally that if employees are moving to a different line, producing a different product, they must change their disposable apron, gloves, and arm covers. If they are moving to a different line that is producing the same product, they do not have to change those items. However, this is not stated in the written program. During IVT collection, EIAOs observed employees moving racks out of coolers and between lines without changing PPE, even when interacting with different product types. They also observed employees who freely move between all lines without directly interacting with product such as those removing garbage, removing product debris from the floors, removing condensation from overhead structures, or performing maintenance.

Further insanitary conditions observed in the establishment that have the potential to spread contamination and *Lm* are as follows. On July 26, 2024, a noncompliance IDG3616071628N/ 1 was issued by In-Plant-Personnel (IPP) describing beaded condensation on the door opening and inside of the Blast Cell #12 dripping over the product. U.S. Retained tags B37563411, B37563412, B37563413, B36563414, B37563415, B37563416, B37563417, B37563419, B37563420 were applied to nine trees of Beechwood Hams (approximately 10,418lbs.). This noncompliance indicates your establishment's failure to maintain sanitary conditions during processing, handling, and storing of the RTE post-lethality exposed products.

On July 27, 2024, a noncompliance IDG3520074727N / 1 was issued by IPP on the RTE side of the plant, in the Blast Cell Hallway, next to Blast Cell #9, when clear liquid was observed falling from a square patch in the ceiling. Ten feet from the patches, a black fan was mounted to the ceiling and was blowing the leaking clear liquid into the Blast Cell Hallway, where 9 trees of uncovered Assorted Hams were stored. These 9 trees were retained by inspection personnel. This indicates your establishment's failure to maintain sanitary conditions.

In summary, the WGS IDs for these isolates from the liverwurst sample are highly related to the clinical outbreak strains, the IVT sample confirmed *Lm* positive for Pallet Jack SH3, combined with no written plans to prevent cross contamination by employees between processing lines, and the noncompliances documented on July 26 and 27, 2024 by IPP for insanitary conditions is evidence that your current SSOP programs, and *Listeria* Control Program are ineffective in supporting that *Lm* is Not Reasonably Likely to Occur (NRLTO) within your Hazard Analysis.

Sanitation Performance Standards (SPS)

NOS Item #1

Your establishment failed to meet the requirements 9 CFR 9 CFR 416.2(b)(1) and (2), 9 CFR 416.2(d), 9 CFR 416.4(a), 9 CFR 416.4(d) and 9 CFR 416.4(b). The Maryland Department of Health Liverwurst product sample that tested positive for *Lm* and the positive *Lm* IVT environmental sample from Pallet Jack SH3 demonstrate that your establishment's current sanitation is inadequate to prevent the creation of insanitary conditions and the adulteration of products.

Sanitation Standard Operating Procedures (SSOP)

NOS Item #2

Your establishment failed to meet the requirements of 9 CFR 416.14.

Your establishment uses Alternative 3 to control *Lm* in post lethality exposed RTE products through the use of sanitation measures only. The positive *Lm* test results from liverwurst product in retail and the IVT environmental swab of Pallet Jack SH3 demonstrate your establishment has been operating under insanitary conditions. Therefore, you cannot support the use of sanitation alone to control *Lm,* and determine *Lm* is a hazard not reasonably likely to occur.

HACCP

NOS Item #3

Your establishment failed to meet the requirements of 9 CFR 417.5(a)(1).

Your establishment's Hazard Analysis has identified *Lm* as a hazard that is not reasonably likely to occur because it is controlled through SSOPs and sanitation. Positive *Lm* test results from liverwurst product in retail and the IVT environmental swab of Pallet Jack SH3 demonstrate this decision making is not supported and therefore, your Fully Cooked Not Shelf Stable HACCP plan is inadequate.

Control of *Listeria monocytogenes* in post-lethality exposed ready-to-eat products

NOS Item #4

Your establishment failed to meet the requirements of 9 CFR 430.4(c)(3) and 9 CFR 430.4(c)(5).

Your establishment has identified it will control exposure of post lethality exposed RTE product to *Lm* though Alternative 3, which relies on the use of sanitation measures only. Result of IVT sampling collected on July 24, 2024, form # 103433961 shows the use of Alternative 3 has been inadequate to control and prevent exposure of RTE product to *Lm*. Your establishment has failed to maintain sanitation in the post-lethality processing environment in accordance with 9 CFR 416. Your establishment uses SSOPs to designate *Lm* control measures. Your establishment has failed to adequately evaluate the effectiveness of these measures in accordance with 9 CFR 416.14.

Summary and Conclusion

Listeria monocytogenes is a pathogen of public health concern especially to high-risk populations including pregnant women, newborns, elderly and people with weakened immune systems and can cause serious and often fatal infections. It has also been known to cause miscarriages and stillbirths. It is widely distributed in the environment, is spread very easily by direct food contact with contaminated surfaces and thrives in the cool, damp conditions present in food processing establishments. *Listeria monocytogenes* is of special concern in facilities that produce ready-to-eat products that are post-lethality exposed.

The wholesomeness of your product is directly dependent on the design and implementation of your sanitation program, adequate *Listeria monocytogenes* control measures and overall maintenance of your facility, including the sanitary procedures conducted in your food production. Evidence demonstrates failure to comply with regulatory requirements identified in 9 CFR 416, including SPS and SSOP requirements, as outlined above. Findings result in FSIS being unable to conclude that sanitary conditions are being maintained, resulting in your establishment's producing and shipping adulterated product. As such, product may have been prepared, packed, or held under insanitary conditions, whereby product may have become contaminated with filth or whereby product may have been rendered injurious to health, rendering the product adulterated (FMIA 21 U.S.C. 601 (m)(4).

In accordance with the Rules of Practice specified in 500.3(a)(4), based on the determination that your establishment failed to maintain sanitary conditions, as required by 9 CFR 416 *et seq*., and 500.3(a)(1), based on the determination that your establishment produced and shipped adulterated product, FSIS is notifying you of the decision to withhold the marks of inspection and expand the suspension of the assignment of inspectors at your establishment to all eight (8) lines in the RTE room under Fully Cooked, Not Shelf Stable HACCP plans. The suspension will remain in effect until you provide the Raleigh District Office with adequate written corrective and preventive measures to assure FSIS that you can demonstrate a program that meets the regulatory requirements.

In accordance with Title 9 CFR 500.5(a)(5), you have the right to appeal the basis for this proposed action by contacting:

[redacted],
Executive Associate for Regulatory Operations
Office of Field Operations
Food Safety and Inspection Service
United States Department of Agriculture
1400 Independence Avenue, SW
[redacted]
Washington, DC 20250
Email: [redacted]
Phone: [redacted] (Main)

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:

[redacted], [redacted]
Enforcement Operations Staff (EOS)
Office of Investigation, Enforcement and Audit (OIEA)
Food Safety and Inspection Service
United States Department of Agriculture
[redacted]
1400 Independence Avenue, SW
Washington, DC 20250
Telephone: [redacted]

If you have any questions, please contact EIAO [redacted] via telephone at [redacted] or via electronic mail at [redacted] or EIAO [redacted] via telephone at [redacted] or email at [redacted]. Additionally, you can contact Raleigh District Office at [redacted] or by fax at [redacted].Sincerely,

Sincerely,

[redacted]

Cc: [redacted]