Review of the Boar's Head *Listeria monocytogenes* Outbreak

January 2025

This report summarizes the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service's (FSIS) initial findings and recommendations for improvements in the wake of a large outbreak of *Listeria monocytogenes (Lm)* illnesses that occurred between May and November 2024 and was linked to liverwurst produced at a Boar's Head facility in Jarratt, VA (M12612).

During July 2024, FSIS worked closely with public health partners to investigate and identify the source of the outbreak. FSIS then moved rapidly to notify the public, ensure all potentially contaminated product was removed from commerce, suspend inspection, and prevent any additional contaminated product from entering commerce.

Once the immediate public health threat had been addressed, FSIS began a thorough review of the outbreak to identify potential contributing factors and evaluate potential regulatory responses. FSIS conducted extensive document reviews and in-person assessments at M12612 and all FSIS-regulated establishments owned and operated under the Boar's Head Provisions Corporate umbrella. The document reviews encompassed 2022 through 2024 and included FSIS-generated inspection records, memoranda, and microbial testing results, as well as establishment programs, procedures, microbial testing results, corrective actions, and findings from Boar's Head's internal investigation at M12612. FSIS also sent investigators to each of these establishments to conduct in-depth Food Safety Assessments (FSA), including targeted environmental and product microbial testing.

Furthermore, FSIS reviewed its own practices and procedures related to *Lm* controls in ready-to-eat (RTE) establishments, including sampling programs, inspector training and instruction, and oversight of establishments under state inspection models. The report concludes with measures to better protect the public from *Lm* informed by the findings. The findings and recommendations included within do not prejudge any ongoing investigations by USDA or any other entity.

Many of the inspection and sampling records used in the review have been requested by the public through Freedom of Information Action (FOIA) requests. To ensure transparency, FSIS will post documents to its FOIA Reading Room as they become available.

Characteristics and History of *Listeria monocytogenes*

Lm is recognized as an important human pathogen. According to the Centers for Disease Control and Prevention (CDC), *Lm* infection (listeriosis) is the third leading cause of death from foodborne illness in the U.S. CDC estimates that each year in the U.S., 1,600 people are infected with *Lm*, and 260 people die from the infection.

Listeriosis is most commonly associated with consumption of RTE foods - foods that are consumed without additional cooking prior to consumption, such as deli meats, dairy products, vegetable row crops and fruits. In the past three years, there have been *Lm* outbreaks associated with queso fresco, peaches, ice cream, leafy greens, enoki mushrooms, deli meat and cheese.

FSIS considers *Lm* to be an adulterant (9 CFR 301.2) in RTE meat and poultry products, meaning that establishments are responsible for ensuring that RTE products contaminated with *Lm* do not enter commerce.

Listeria species (spp.) are considered an indicator organism (i.e., a microorganism used to indicate the presence of pathogens) for *Lm*. Environments that enable the growth and harborage of other *Listeria* species would also support *Lm*. Harborage sites provide an ideal place for *Lm* to establish and multiply.

Listeria survives and grows at cool temperatures as low as 34°F (1°C). Because of its growth and survival characteristics, *Listeria* usually persists in the environment and is commonly referred to as a harborage organism. It can cross-contaminate food contact surfaces (FCS) and foods. Transfer of the bacteria from the environment or from the raw processing environment to RTE products is a particular hazard of concern. Improper sanitation and product handling can lead to the transfer of *Lm* to RTE meat and poultry products, causing them to become adulterated. Because RTE meat and poultry products do not require cooking prior to being consumed and are often held at refrigerated temperatures, where the pathogen can survive and grow, these products provide an ideal environment for the bacteria to grow once product is contaminated.

Illness Outbreak Summary

On July 12, 2024, FSIS opened an investigation into a multistate outbreak of listeriosis linked to retail-sliced deli meats. The traceback investigation, done in conjunction with state partners, narrowed the source to M12612. CDC declared the outbreak over on November 21, 2024, reporting that, of the 61 people from 19 states infected with the outbreak strain of *Lm,* 60 were hospitalized and 10 died. The median age of those who became ill with the outbreak strain of *Lm* is 78 years old, including 31 men and 30 women. Isolates from two *Lm* positive liverwurst samples, produced at establishment M12612 and tested by state partners in Maryland and New York, matched the outbreak strain using whole genome sequencing (WGS).

Based on the foodborne illness outbreak, FSIS conducted a Public Health Risk Evaluation (PHRE), in accordance with FSIS Directive 5100.4, *Public Health Risk Evaluation Methodology*.

A PHRE is a thorough review of all available, relevant inspection records and may be used to determine whether an FSA is warranted. An FSA is an in-depth assessment (including in-plant review) of an establishment's food safety system to verify that meat, poultry, or egg products are safe, wholesome, and produced in accordance with FSIS statutory and regulatory requirements. An FSA may include intensified verification testing (IVT)—a sampling protocol for meat and poultry products under which FSIS tests product, FCS and non-food contact surfaces (NFCS; environmental sample) for *Lm* or *Salmonella*.

Upon completion of the PHRE, FSIS determined that an FSA was warranted. FSIS arrived at the establishment on July 22, 2024, to prepare for an FSA and conduct IVT sampling. On July 24 - 25, 2024, FSIS enforcement, investigation and analysis officers (EIAO) conducted IVT sampling and collected a total of 81 samples (20 product samples, 40 FCS samples, 20 NFCS samples, and 1 brine sample).

On July 25, 2024, the Maryland Department of Health confirmed that an unopened package of liverwurst product, produced by M12612 and collected at retail, was positive for *Lm*. That same day, FSIS suspended inspection of all operations on the production line used to produce liverwurst.

On July 26, 2024, M12612 recalled all liverwurst products in commerce and additional deli meat products (approximately 207,528 pounds) that were produced on the same line and day as the confirmed *Lm* positive liverwurst sample reported by the Maryland Department of Health. On July 29, 2024, WGS results from the Maryland sample confirmed that the liverwurst sample was contaminated with the outbreak strain of *Lm* and an IVT sample taken from a pallet jack (equipment used to lift and move pallets) that traveled throughout the raw and RTE areas of the plant was also confirmed *Lm* positive by FSIS (the remaining IVT samples tested negative). As a result, FSIS suspended inspection on all production lines at M12612 that same day. The establishment expanded the recall on July 30, 2024, to include all products produced at M12612 between May 10, 2024, and July 29, 2024. The recall involved over 7 million pounds of RTE meat and poultry products.

On September 13, 2024, Boar's Head announced that it would indefinitely close M12612.

FSIS Assessment of Factors Contributing to Outbreak Associated with Boar's Head Establishment M12612

M12612 is a large establishment in Jarratt, VA, that received its grant of inspection in April 1984. The establishment produced a variety of RTE deli meats and hot dogs including hams, bologna, liverwurst, Canadian bacon, head cheese, franks, and kielbasa, which were distributed directly to retail outlets. The facility has a federal grant of inspection and was inspected by the Virginia Department of Agriculture and Consumer Services (VDACS), through a Talmadge-Aiken (TA) cooperative agreement, established under the Talmadge-Aiken Act of 1962 ("the TA Act;" 7 U.S.C. 1633; see below for more detail).

Findings related to M12612

FSIS reviewed inspection documents and establishment sampling data from January 2022 to September 2024 and conducted in-person observations as part of this review. Based on records and observations, FSIS identified several factors that may have contributed to the outbreak.

A notable contributing factor was the facility's inadequate sanitation practices. Observations by VDACS inspection personnel documented in noncompliance records (NR) demonstrated multiple instances of noncompliance with Sanitation Standard Operating Procedures and Sanitation Performance Standards. While sanitary conditions were required to be restored for each documented noncompliance, repeated instances of insanitary conditions can present opportunities for growth or sustained presence of *Lm*. Documented instances of noncompliance included:

- *Product Residue:* Inspectors identified the presence of meat and fat residue from the previous day's production on equipment, including packaging equipment and in the RTE processing area during preoperational sanitation checks. Residue can provide a substrate for *Lm* to survive and grow in the food processing environment and form biofilms, which can become more resistant to cleaning regimens. Biofilms are thin layers of bacteria that can form on equipment and other surfaces (similar to plaque on teeth). Once biofilms form, they must be removed by scrubbing or other mechanical action.

- *Condensation:* Inspectors identified multiple instances of condensation in the RTE environment (e.g., dripping condensate on exposed product and a fan blowing condensate directly on products).
- *Structural and Facility Problems*: Inspectors observed facility and structural-related issues (e.g., cracks, holes and broken flooring) that could hold moisture and contribute to wet conditions. Additional conditions documented included rust, beaded condensation and peeling caulk.

Additional considerations assessed by FSIS included the establishment's construction activities, sampling history, sampling programs and raw and RTE separation practices.

Review of the other Boar's Head Facilities

On September 5, 2024, FSIS broadened the scope of its review of the *Lm* illness outbreak to include a review of all FSIS-regulated establishments owned and operated under the Boar's Head Provisions Company corporate umbrella. EIAOs conducted FSAs at other Boar's Head establishments located in Arkansas, Indiana, Michigan, and Virginia. As part of the FSAs, FSIS also conducted IVT sampling for *Lm* at these Boar's Head facilities, and ensured any identified deficiencies were corrected and monitored in both the short- and long-term.

Short-term Opportunities for Strengthened FSIS Oversight

In addition to assessing M12612 and the other Boar's Head facilities, FSIS' review also included a deep dive into its processes and procedures related to *Lm* controls and agency inspection and oversight in RTE establishments. Together this work yielded several key areas for improvement including those related to sampling, inspector training, oversight over Talmadge-Aiken federal plants staffed by state inspectors, and the future of the agency's *Listeria* regulatory policy.

As outlined in the agency's Dec. 17th announcement, many of these new policies and practices are already being put in place.

Enhancing FSIS' Regulatory and Sampling Approach to *Listeria*

FSIS-regulated establishments are required to produce safe, wholesome and unadulterated products before releasing them into commerce. Establishments that produce RTE products must follow applicable FSIS regulations, including requirements relevant to comprehensive control of *Lm* in regulated establishments. FSIS regulations include: Sanitation Performance Standards (9 CFR 416.1-416.5), Sanitation Standard Operating Procedures (9 CFR 416.12-416.16), and Hazard Analysis and Critical Control Point (9 CFR 417).

In addition, FSIS' *Listeria* Rule (9 CFR 430.4) requires RTE establishments to control *Lm*, with measures prescribed in the regulations based on the unique characteristics of the product and/or controls applied by the establishment. These regulations require an establishment to identify one of the following three "Alternatives" to incorporate into its operation:

- **Alternative 1**: The process includes a post-lethality treatment (PLT) to reduce or eliminate *Lm* in the product and an antimicrobial agent or process (AMAP) to limit or suppress growth of *Lm* in the product.

- **Alternative 2:** The process includes a PLT to reduce or eliminate *Lm* in the product (Alt 2a) or AMAP to limit or suppress growth of *Lm* in the product (Alt 2b).
- **Alternative 3**: The process uses sanitation alone to control *Lm* in the processing environment to prevent product contamination. This alternative was used at M12612.

FSIS' regulatory requirements and guidance to industry, as well as the agency's sampling frequency, varies depending on the alternative the establishment incorporates into its operation. Regardless of the alternative incorporated, RTE products are considered adulterated if they are contaminated with *Lm* or pass over a surface that is contaminated with *Lm*.

To enhance its regulatory and sampling approach to *Lm* FSIS will:

- **Add broader *Listeria* species testing to all samples of RTE product, environmental and food contact surfaces.** FSIS laboratories currently test these samples for *Lm*, which is the specific type of *Listeria* species that causes illness. However, adding additional species testing to the agency's regulatory framework will help provide more information about the effectiveness of a facility's sanitation program and can signal to FSIS if follow up is needed (for example, an FSA, intensified sampling, or enforcement actions).

- **Leverage the expertise of its National Advisory Committee on Microbiological Criteria for Foods (NACMCF).** NACMCF is a federal advisory committee that provides scientific advice and recommendations to USDA and other government agencies on microbiological and public health issues. The committee will be given the specific charge of reviewing the agency's regulatory approach to *Lm*. The committee's input will be used to guide more long-term policy changes.

Equipping FSIS Inspectors with Updated Training and Tools to Recognize and Respond to Systemic Food Safety Issues

Review of records and data from M12612 indicates a pattern of conditions that presented an elevated risk for *Lm* contamination.

In addition to documenting NRs and verifying corrective actions, inspection personnel should consider whether repeated noncompliance findings collectively signal a broader systemic failure at an establishment. In order for inspectors to elevate systemic problems with an establishment's food safety system for action, they must have the ability and tools to recognize patterns and determine when multiple deficiencies suggest a systemic issue. This broadly applies to all state TA and FSIS inspectors.

FSIS is equipping its personnel with the training and tools to recognize and respond to systemic food safety issues, through:

- **Updated instructions and training for food safety inspectors to better equip the workforce to recognize and highlight systemic problems in a standardized way.** Agency inspectors will receive updated instructions and training, and FSIS field supervisors will routinely review these instructions with inspectors to ensure full understanding and

appropriate application. Inspectors will also receive supplemental *Lm* control training designed to help strengthen inspectors' understanding of the regulatory requirements in FSIS' *Listeria* Rule and how to verify establishments have designed and implemented food safety systems that comply with those requirements.

- **Prioritized FSAs (in-depth food safety reviews) at RTE meat and poultry facilities.** In fiscal year (FY) 2025, FSIS is prioritizing completion of FSAs at RTE meat and poultry facilities that rely exclusively on sanitation measures to control for *Listeria*. These reviews will provide information about the plants individually and collectively. FSIS will publicly share findings and trends from these assessments that result in any future policy or process changes to target this microorganism.

- **Updated protocols for FSA follow-up.** FSIS field supervisors will conduct in-person, follow-up visits when systemic issues are identified during an FSA. Follow-up visits by FSIS field supervisors will bolster oversight from more senior inspection staff to ensure a facility fully addresses issues identified during an FSA and could inform enforcement action by FSIS. A record of FSIS enforcement actions are published quarterly. Field supervisors will work with inspectors to ensure the facility stays in compliance.

- **Revised establishment-review alert criteria.** One significant criterion used to guide a district office's decision to conduct a PHRE, which typically precedes an FSA, is a monthly list of facilities with higher rates of noncompliance related to public health that is generated using an algorithm. Using additional data from the new weekly verification of *Lm*-related risk factors, FSIS intends to update its algorithm and criteria to better identify high-risk facilities, which may include updates to FSIS Directive 5100.4, *Public Health Risk Evaluation Methodology*.

Tightening Oversight of Regulated Establishments, Including Those Under State Inspection Models

FSIS oversees controls related to *Lm* at all Federally-inspected establishments.

M12612 was inspected by VDACS as part of a TA cooperative agreement. The TA Act of 1962 (7 U.S.C. 1633) provides FSIS with the authority to enter into agreements with a State Department of Agriculture, or any other State agency responsible for its meat or poultry inspection program, to perform inspection duties in federal establishments on behalf of FSIS.

These state inspectors receive the same FSIS training and meet the same duty requirements as Federal inspectors. They comply with all applicable Federal statutes and regulations and follow FSIS Directives and Notices; they are notified of updates to FSIS directives and notices through email and other electronic notifications in the same way as FSIS personnel. They document their inspection findings in FSIS' Public Health Information System (PHIS). Because TA establishments hold a grant of Federal inspection, they can ship their products both within and outside the state and may export product. Historically, TA cooperative agreements were used to help provide inspection services in rural or remote areas.

Funds appropriated specifically to cover state inspection costs are divided among the TA and other state inspection programs per statute, subject to funds availability. FSIS has historically aimed to

meet the 50% reimbursement rate for state Meat and Poultry Inspection and TA costs, though funding has not been sufficient in recent years to meet that level of support. Appropriated funding to FSIS for MPI and TA has not increased since FY 2020, leaving the states to absorb increased costs.

There are currently nine states (Alabama, Georgia, Illinois, Mississippi, North Carolina, Oklahoma, Texas, Utah, and Virginia) with TA cooperative agreements. In addition to TA cooperative agreements, FSIS has historically used the authority from the TA Act to enter into Cross-Utilization (CU) agreements that have operated in a functionally similar way to TA since 2004. FSIS currently maintains CU cooperative agreements with three states (Louisiana, South Carolina, and Vermont).

After reviewing existing practices, FSIS has identified and implemented the following actions to strengthen oversight of establishments, including those inspected by states under TA cooperative agreements:

- **Inspectors, both in TA facilities and other Federally-inspected facilities, are now verifying specific *Lm*-related risk factors at all RTE facilities weekly.** These risk factors include changes in physical plant modifications, such as new construction; indicators of sanitation problems, such as condensation, roof leaks, damaged equipment, or cracked floors; and *Listeria* species or *Lm* positive test results from company testing. FSIS district offices, agency field supervisors and inspectors will review, analyze and consider the weekly data from each facility to determine if there are systemic issues that warrant further action, such as an FSA, intensified sampling, or enforcement steps. In the long-term and based on funding availability, FSIS will explore enhancements to PHIS to include specific data fields for *Lm* risk factors so that these data are available for alerts, reports, algorithms, and routine data analysis related to *Lm* and RTE products. Additional PHIS alerts would proactively flag specific conditions related to *Lm* for FSIS in-plant personnel, supervisors and district management.

- **FSIS has clarified state and Federal requirements for consistent oversight of the TA program through updated cooperative agreements and instructions.** Through updated cooperative agreements with each participating state, FSIS is setting specific requirements, including clear expectations for oversight and enforcing federal food safety laws, comprehensive federal training for TA inspectors, and enhanced regular coordination with FSIS. FSIS has also designated field and headquarters positions assigned to TA oversight, and has clarified training requirements and criteria to start, maintain and terminate state inspection coverage of an establishment.

Long-Term Measures to Protect the Public from *Listeria monocytogenes*

FSIS' *Listeria* Rule and related *Listeria* control activities have led to significant declines in *Lm* detections associated with FSIS-regulated products over the past two decades. However, FSIS' review of the outbreak associated with M12612, as well as other recent recalls due to *Lm*, points to the need for the agency to examine and enhance all aspects of its approach to *Lm*. Since FSIS' *Listeria* Rule went into effect over 20 years ago, testing technology has evolved, consumer consumption patterns have changed, and food production and supply chains are more

consolidated. Moving forward, it is critical that FSIS consider this changing landscape to modernize its approach to regulating *Lm*.

Enhance FSIS' Regulatory and Sampling Approach to *Listeria*

A deeper examination of the agency's *Listeria* Rule is needed, with the right expertise and stakeholder engagement before making recommendations for long-term and comprehensive changes to FSIS' regulatory approach. A foundational piece of the agency's commitment to modernize its approach to *Lm* will be provided by the NACMCF, the advisory committee charged with providing impartial scientific advice and recommendations to the USDA and other government agencies on microbiological and public health issues relative to the safety of the U.S. food supply. On December 20, 2024, USDA began soliciting nominations for new members of the committee, including those with specific expertise in *Listeria*. The new members will thoroughly examine FSIS' regulatory approach to *Lm* and provide science-based recommendations by 2026 on how to make it more effective.

FSIS' review of its existing regulatory approach to control *Lm* in post-lethality exposed RTE products will continue to be grounded in the fundamental determination that *Lm* is an adulterant in RTE meat and poultry products. *Lm* in these products has a zero-tolerance standard, which means that product contaminated with any detectable amount of *Lm* cannot be released in commerce; if it has been, FSIS will request a recall or issue a public health alert to notify consumers.

In its comprehensive review of the *Listeria* Rule and existing policies, the agency will address a wide range of topics, including whether FSIS should: 1) determine whether to require establishments to perform additional testing for *Listeria* spp. and take corrective actions in response to positive *Listeria* spp. results, 2) determine whether to require RTE establishments to routinely submit to FSIS through the External Lab Results System (electronic system to accept lab sampling results from outside FSIS) all microbial data used to support their Hazard Analysis and Critical Control Point system, and 3) strengthen the requirements that establishments producing these products document the steps they are taking to prevent product adulteration by *Lm,* including testing. Additionally, FSIS will consider any additional revisions to the regulations that may be needed, including to Alternatives 1–3. FSIS anticipates robust and useful stakeholder input on any future proposal to update the *Listeria* Rule.

At the same time the agency reexamines *Lm* regulations and policies, it will also review and consider enhancing its RTE sampling programs to more effectively identify potential *Listeria* contamination or harborage at the facilities it regulates.

FSIS currently regulates approximately 2,600 RTE establishments. On a routine basis, FSIS inspection personnel collect, and the labs analyze, finished RTE product samples throughout the year. FSIS collects a minimum of two product samples per year and a maximum of one per month (12 per year) at these establishments under its routine RTE sampling program for *Lm*. The frequency of sampling is determined based on a variety of factors (e.g., establishment size, sampling history, product type and alternative used).

Looking across RTE establishments in FY 2023, for its routine RTE sampling program, FSIS collected approximately 15,000 samples at these establishments, and 0.187% of the samples were positive for *Lm*. M12612 was sampled by FSIS at the highest frequency (monthly), yet this sampling did not identify the establishment's *Listeria* problem.

By contrast, FSIS is exploring establishing a new routine sampling program for inspection personnel to collect FCS and NFCS swab samples from the RTE processing environment based on consideration of production volume, *Lm* control alternative, and other risk factors identified in the establishments. These samples would be analyzed for *Lm* and *Listeria* spp. using the new method FSIS will implement in January 2025. This enhancement would improve FSIS' sampling program by providing additional information about sanitation.

Additionally, FSIS will evaluate incorporation of agency *Listeria* spp. results, certain types of NRs, and additional relevant data into FSIS' routine sampling algorithm, which will ensure that adequate samples are collected at the highest-risk establishments. After FSIS has implemented any of the potential changes to the RTE sampling program described above, the agency will evaluate all RTE sampling programs (RTE product, R*Lm* and IVT sampling, any new FCS or NFCS sampling program,) to determine their effectiveness. This review will inform whether additional changes will need to be made to these programs, including to sampling frequencies, locations for sampling, and whether additional FSIS sampling should occur in the event of repeat *Listeria* spp. positives from establishment testing.

Next Steps

FSIS has already begun to implement several of the short-term actions identified in the report and is committed to swift implementation of the remaining actions. The short-term actions are intended to strengthen the agency's inspection and oversight by enhancing its ability to proactively identify and respond to the types of systemic problems that could lead to outbreaks.

At the same time, FSIS will continue to work toward its long-term vision to modernize the agency's regulatory approach to *Lm*. The long-term work FSIS outlined above is ambitious. It will take consistent commitment over the course of several years and will require significant stakeholder engagement and expertise to complete in a meaningful and comprehensive way. This work is necessary to protect public health.

Any expanded approach to *Listeria* control will require commensurate funding. As requested in the FY 2025 President's Budget, additional resources are necessary for the agency to continue to meet its mission to keep meat, poultry, and egg products safe and wholesome, and these findings are in addition to the significant resource needs that were previously identified in that request.

Lm continues to be a pernicious pathogen and the cause of illness outbreaks and recalls despite continued efforts to mitigate its presence. Protecting the public from *Lm* and mitigating this public health challenge remains a top priority for FSIS.