



October 19, 2023

BrucePac
Establishment 51205/P-51205
1950 Business 70
Durant, OK 74701

Sent via email & USPS

Attention: Mr. Robert Bruce, Owner

This letter is in regard to events that occurred on October 18, 2023, at BrucePac, Establishment 51205/P-51205, Durant, Oklahoma.

On October 18, 2023, Ms. (b)(6) Consumer Safety Inspector (CSI), was informed by CSI (b)(6) in the Fort Worth circuit that three hundred ninety cases of Fully Cooked shredded white meat chicken would be returning from (b)(4) to BrucePac at approximately 12:00 p.m. The reason the product was being returned was because of a foreign material concern; apparent paper contamination. BrucePac originally sent five hundred eighty cases to (b)(4) which discovered the foreign material during processing, but after they had processed one hundred ninety-two cases.

CSI (b)(6) was at another establishment on her patrol when she was informed of the return of the product. CSI (b)(6) spoke with Ms. (b)(6) Q.A. Manager, about the return of the product during a subsequent telephone conversation. CSI (b)(6) told Ms. (b)(6) that she, the CSI, would have to be present to break the seal on the product because it had been applied FSIS, and that it would probably be a little while before she could get back to BrucePac due to export obligations.

Before CSI (b)(6) was able to report back to BrucePac, Ms (b)(6) called and informed her that someone had removed the seal on the truck and the product had already been unloaded. Once CSI (b)(6) arrived at BrucePac, she verified that all of the product that was documented on FSIS Form 7350-1 and on the shipping Log/bill of Lading was accounted for that had been returned to the establishment. The product had been unloaded and was sitting on the shipping dock.

CSI (b)(6) retrieved the USDA seal #97347232 which had been applied by CSI (b)(6) and she retained all of the three hundred ninety cases of product with U.S. Retained tag #B-39138324; now stored in the North freezer. The product codes are: B21CC4543, B4281841, B4281834, B4281842, B4281844, B4281835, B4281840 and B4281843. The code dates on the product are: 0823302, 08233347 and 0823349.

The Federal Meat Inspection Act (FMIA), 21 United States Code (USC), Section 602 (et seq.) and the Poultry Products Inspection Act (PPIA), 21 USC 451 (et seq.), provide that it is essential in the public interest that the health and welfare of consumers be protected by assuring that poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged.

Food Safety and Inspection Service
Office of Field Operations
Dallas District Office
1100 Commerce Street, Room 516
Dallas, TX 75242
Voice 214-767-9116 Fax 844-622-0080
An Equal Opportunity Provider and Employer

Under the authorities of the Acts, the Food Safety, and Inspection Service (FSIS) has developed Rules of Practice regarding enforcement in Title 9 of the Code of Federal Regulations (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 Federal Inspection.

This letter serves to inform you of the seriousness of violating a Regulatory Control Action.

9 CFR 500.1(a) defines a regulatory control action as, *the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product*. Additionally, 9 CFR 500.3 states, *(a) FSIS may take withholding action or impose a suspension without providing the establishment prior notification because; ... (5) The establishment violated the terms of a regulatory control action ...*

It is the establishment's responsibility to assure that a regulatory control action is not violated, and that employees are trained accordingly. Further, it is strongly suggested that you take any and all steps to prevent these violations from recurring. Only USDA FSIS personnel have the authority to end a Regulatory Control Action and/or remove USDA Retain/Reject tags.

Please send a written response to this event and proffer preventative measures to assure FSIS that every effort will be made prevent a recurrence. Please provide Dr. (b)(6) Frontline Supervisor, with a response within five working days from the receipt of this letter. You can email your response to (b)(6)@usda.gov.

Sincerely,

(b)(6)

Jennifer Beasley-McKean, DVM
District Manager

cc:

Dr. (b)(6), Frontline Supervisor, Oklahoma City, OK
Inspector in Charge, Establishment 51205/P-51205, Dallas, TX



October 5, 2024

BrucePac
Establishment 51205/P-51205
1915 Business 70
Durant, OK 74701

Sent via electronic mail & USPS

Attention: Mr. Robert Bruce, Owner

NOTICE OF INTENDED ENFORCEMENT

This letter serves as official notification by the Food Safety and Inspection Service (FSIS) of our intent to withhold the marks of inspection and suspend the assignment of inspection program personnel (IPP), with prior oral notification, for your Fully Cooked Not Shelf Stable Hazard Analysis and Critical Control Point (HACCP) processes at BrucePac, Establishment M51205. The decision to institute this enforcement action is in accordance with Title 9 of the Code Federal Regulations (CFR), Rules of Practice 500.4(a) based on the determination that your Fully Cooked Not Shelf Stable HACCP processes are inadequate as defined in 9 CFR 417.6 (a)(c)(d) and (e) due to your establishment's failure to comply with regulatory requirements.

Background/Authority

The Federal Meat Inspection Act (FMIA), 21 United States Code (USC) Section 601 (et. seq.), and The Poultry Products Inspection Act (PPIA), 21 USC 451 (et. seq.), provide 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 Acts give 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. These Acts provide 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 the Acts, 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

From October 3, through October 4, 2024, Mr. (b)(6) Enforcement Investigations and Analysis Officer (EIAO) and Mr. (b)(6) Supervisory Enforcement Investigations and

Food Safety and Inspection Service
Office of Field Operations
Dallas District Office
1100 Commerce Street, Room 516
Dallas, TX 75242
Voice 214-767-9116 Fax 844-622-0080
An Equal Opportunity Provider and Employer

Analysis Officer (SEIAO), assessed the food safety systems in use at your facility. The assessment was performed at the request of the Dallas District Office due to three product samples FSIS collected at Taylor Farms establishments in New Jersey, Florida, and Texas. Your firm provided these ready-to-eat (RTE) chicken products to Taylor Farms to be further processed into RTE salad products. These chicken products were found to be positive for *Listeria monocytogenes* (*Lm*).

Based on the analysis and evaluation of your establishment's Fully Cooked Not Shelf Stable (FCNSS) HACCP plan and hazard analysis, FSIS has become concerned that your establishment has failed to ensure compliance with the HACCP regulatory requirements of 9 CFR 417 may not be sufficient to ensure the safety of products at this establishment.

The following information is provided to support the Notice of Intended Enforcement at your facility:

Fully Cooked Not Shelf Stable HACCP
9 CFR 417.3(b), 417.4(b), and 417.5(a)(1).

Observations in your processing and packaging areas show that post-lethality exposed RTE products are handled at several points prior to final packaging by plant employees, conveyors, totes and equipment. For example, frozen sliced, diced, or shredded chicken breast products are filled into blue plastic lined combo totes via conveyor belts from each line spiral freezer. These combo totes are moved with pallet jacks to the packaging area. Combo totes are placed in combo tote dumpers. The combo totes are lifted to dump the product on to vibrating feed tables to incline conveyors which go to a bucket Ishida-style system. Products sent to Taylor Farms are all packaged in the same production room and are dumped loosely into boxes with plastic liners. Plastic liners are folded over but not sealed.

A review of the hazard analysis for your Fully Cooked Not Shelf Stable HACCP system shows that you have determined (b)(4) based on your controls for *Lm*. Through this program you have chosen to control *Lm* by use of

(b)(4)

A review of sampling records from your *Listeria* control program shows you had (b)(4) sample results as follows:

(b)(4)

Based on these (b)(4) results your firm initiated corrective actions on (b)(4) and the (b)(4) (b)(4). These corrective actions included intensified cleaning and sanitizing, investigatory sampling/re-sampling, and product hold and test procedures. However, there is compelling evidence that your corrective actions have been ineffective. Specifically, you produced fully cooked, RTE chicken products for Taylor Farms in Texas on 9/12/2024, after the implementation of your corrective actions for the (b)(4) *Lm* samples. This product was found to be positive for *Lm* on 9/30/2024, in a sample collected by FSIS.

Additionally, you produced fully cooked, RTE chicken products for Taylor Farms in New Jersey on 6/19/2024, and Taylor Farms in Florida on 7/2/2024 and 7/8/2024. FSIS in-plant personnel collected samples of these products on 9/24/24 and 9/10/14, respectively, and they were found to be positive for *Lm*. It should be noted that the products produced for the three Taylor Farms facilities were all diced or shredded chicken that was cooked, frozen, and packaged in the same production room. Finished products are loosely placed into boxes with plastic liners that are folded over but not sealed.

You received notification from Taylor Farms of the positive *Lm* results in samples collected by FSIS at their New Jersey, Florida, and Texas facilities. You were unable to provide evidence you performed a reassessment of your HACCP system regarding *Listeria* controls considering this information as required by 9 CFR 417.4(b)(4). The last time you reassessed your Fully Cooked Not Shelf Stable HACCP plan was August 13, 2024. Further, since you became aware of positive test results for *Lm* in products produced in your facility, decisions in your hazard analysis have not changed. FSIS believes there is compelling evidence that you produced the *Lm*-positive RTE products shipped to the Taylor Farms facilities in New Jersey, Florida, and Texas. Based on this information you have not supported a decision that (b)(4) as required by 9 CFR 417.5(a)(1). This results in a determination that your HACCP system is not validated as required by 9 CFR 417.4.

Observations made by the EIAOs during the assessment of your food safety systems revealed vulnerabilities and concerns regarding possible *Listeria* harborage and contamination sites:

- The underside of the conveyor belt on Line 1 for the slicing machine contacts a stainless-steel grated partition with accumulated buildup of small chicken meat particles forming an approximately in a one inch wide and quarter inch thick accumulation. Product exits the spiral freezer on conveyor belt on the north side of the spiral freezer which dumps onto an incline combo tote filler. The squared exit hood and opening had heavy accumulations of frozen condensate of varying thickness from a half inch to over an inch. Exposed frozen product passes through the hood and freezer opening.
- On Line 2 and Line 4, product exits the spiral freezers on conveyor belts on the north side of the spiral freezers. Product is dumped onto hooded ramps which lead to conveyors to a combo tote filler. The upper portion of the dump ramps under the freezer conveyor belt had heavy accumulations of frozen condensate of varying thickness which resembled a small snow drift with chicken pieces.
- In the (b)(4) packing area an accumulation of frozen condensation a quarter inch to over a half-inch thickness was observed on the upper and lower side of the conveyor belt paddle perpendicular to the conveyor belt.
- The (b)(4)-style packing machines had frozen condensate on several dump buckets.
- The production and packing areas have water accumulation on the floors in various areas. This is a high moisture environment. The firm cleans their inline slicing and dicing machines on a three-to-four-hour schedule during operations. These machines are pushed to a cleaning room on the southeast side of the building passing through a hanging clear plastic curtain. The roller garage-style door has a half inch gap under the door going to the loading dock. The wall footings have a clear or floor covering sealant which has come loose or missing, creating harborage points in several location along the perimeter walls.
- Line 1 and the (b)(4) packaging equipment were implicated in confirmed positive *Listeria monocytogenes* plant samples.

Although freezing may suppress or limit *Listeria* growth, it doesn't necessarily kill the organism. The spiral freezers have many areas that are difficult to reach or are inaccessible. Due to the size of the units, they cannot be disassembled completely for a thorough cleaning. Freezers can be damaged during operation, cleaning, and sanitizing. As the damage occurs, it creates even more harborage points for microorganisms. As the freezer is defrosted for thorough cleaning, the warmer temperatures allow existing *Listeria* to grow. The condensation created from the thaw can also contaminate other surrounding surfaces.

Conclusion

A HACCP system should be designed to identify, evaluate, and control hazards which are considered significant, relative to food safety and public health. The focus should be on the prevention of food safety hazards to ensure the resulting products are safe and will not cause illness or harm to the consumers of those products as required by the FMIA and PPIA. Failure to produce products in this manner may result in products potentially injurious to health. Based on the findings described within the preceding paragraph(s), FSIS has determined that continued production of products within your Fully Cooked Not Shelf Stable HACCP process may result in their adulteration. In summary, your establishment has failed to effectively maintain sanitary conditions as required in 21 U.S.C. 456 Section 7, of the PPIA based on the lack of effective food safety process controls as required in 9 CFR Part 416, 417 and Part 430 *et. seq.* Conditions in your establishment are such that product can become adulterated as defined by 21 U.S.C. 453, Section 4(g)(1 and 4) of the PPIA which state that the term adulterated may be applied to a product "*If it bears or contains any poisonous or deleterious substances which may render it injurious to health...*" and "*...if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health.*"

In accordance with the Rules of Practice, 9 CFR 500.4, which state "*FSIS may take a withholding action or impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance because: (a) The HACCP system is inadequate, as specified in §417.6 of this chapter, due to multiple or recurring noncompliances.*" Accordingly, FSIS is notifying you of our intent to withhold the marks of inspection and suspend the assignment of inspectors from your Fully Cooked Not Shelf Stable operations at your establishment.

Please provide this office with a written response concerning this NOIE within three (3) business days from the date of your receipt of this letter, no later than close of business October 8, 2024. We will determine further action, if any, based on your response. Your written response is expected to explain how you will bring your establishment back into compliance with the regulatory requirements. Your response should include the specific corrective actions and preventative measures that have been or will be taken in response to the noncompliance(s) identified and copies of all documents associated with the proffered corrective actions.

You may submit your response to me by fax to 844-622-0080, or by electronic mail to jennifer.mckean@usda.gov.

In accordance with 9 CFR 500.5(b)(4), you may contest the basis for this proposed action by contacting:

BrucePac
Notice of Intended Enforcement
October 5, 2024

5

Sherri Johnson
Executive Associate for Regulatory Operations
Office of Field Operations
Food Safety and Inspection Service, USDA
1400 Independence Ave S.W.
Room 3164 South Building
Washington, DC 20250
Mobile: (b)(6)
Sherri.Johnson@usda.gov

If you have any questions, please contact Mr. (b)(6) Supervisory Enforcement Investigations Analysis Officer, via telephone at (b)(6) or via electronic mail at (b)(6)@usda.gov. Additionally, you may contact Dallas District Office at 214-767-9116, or by fax at 844-622-0080.

Sincerely,

Digitally signed by JENNIFER BEASLEY
MCKEAN
DN: c=US, o=U.S. Government,
ou=Department of Agriculture,
0.8.2342.19200300.100.1.1=12001000063383,
cn=JENNIFER BEASLEY MCKEAN
Date: 2024.10.05 15:59:29 -0500
JENNIFER BEASLEY
MCKEAN

Jennifer Beasley-McKean, DVM
District Manager

cc:
Dr. (b)(6) Frontline Supervisor, Oklahoma City, OK
Inspector in Charge, Establishment 51205/P-51205, Durant, OK



October 9, 2024

BrucePac
Establishment 51205/P-51205
1915 Business 70
Durant, OK 74701

Hand-delivered and sent via USPS

Attention: Mr. Robert Bruce, Owner

NOTICE 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 BrucePac, Establishment 51205/P-51205, located at 1915 Business 70, Durant, Oklahoma. This letter follows the verbal notification of the suspension action, provided by Dr. Jennifer Beasley-McKean, District Manager, to you at approximately 2:00 p.m. on October 8, 2024. This action includes all Fully Cooked, Not Shelf Stable Hazard Analysis Critical Control Point (HACCP) processes employed by your establishment.

The decision to institute this enforcement action is in accordance with Rules of Practice, Title 9 of the Code Federal Regulations (CFR) Part 500.3(a)(1) and (4) based on the determination that your establishment shipped adulterated product as defined in 21 U.S.C. 602 and that sanitary conditions are such that products in the establishment are or would be rendered adulterated.

Background/Authority

The Federal Meat Inspection Act (FMIA), 21 United States Code (USC) Section 601 (et. seq.), and The Poultry Products Inspection Act (PPIA), 21 USC 451 (et. seq.), provide 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 Acts give 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. These Acts provide 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 the Acts, 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

Food Safety and Inspection Service
Office of Field Operations
Dallas District Office
1100 Commerce Street, Room 516
Dallas, TX 75242
Voice 214-767-9116 Fax 844-622-0080
An Equal Opportunity Provider and Employer

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

FSIS collected samples of ready-to-eat (RTE) products produced at Taylor Farms, Est. 44818/P-44818 on September 10, 2024. This sample confirmed positive for *Listeria monocytogenes* (*Lm*) on September 19, 2024. FSIS collected a sample of RTE product produced at Taylor Farms, Est. 34513A/P-34514A on September 24, 2024. This sample confirmed positive for *Lm* on October 1, 2024. FSIS collected a sample of RTE product produced at Taylor Farms Texas, LLC, Est. 34733/P-34733 on September 25, 2024. This sample confirmed positive for *Lm* on September 30, 2024. FSIS also submitted 5 unopened boxes of Grilled Chili Lime Seasoned Diced Chicken produced on September 12, 2024, for laboratory analysis. This product was shipped to Taylor Farms Est. 34733/P-34733 and was used to make the salad that was sampled by FSIS on September 25, 2024. The unopened 35-lb boxes produced by your establishment were submitted to the laboratory on October 4, 2024. On October 8, 2024, the samples were determined to be presumptive positive for *Lm*. Additionally on October 8, 2024, FSIS determined that the three *Lm* isolates from the samples collected at the three Taylor Farms establishments are closely related (within 7 alleles) by Whole Genome Sequencing (WGS). This evidence indicates the source of *Lm* originated at your establishment, and not at your customers' establishments.

There is compelling evidence that corrective actions your establishment took in response to the (b)(4) product samples that you collected which were produced in (b)(4) have been ineffective. You performed intensified cleaning and sanitation and collected additional samples of food contact surfaces and the environment between (b)(4) (b)(4). You also reassessed your Fully Cooked Not Shelf Stable HACCP plan on August 13, 2024. However, product produced on September 12, 2024, was still confirmed to be adulterated with *Lm*. You received notification from Taylor Farms of the positive *Lm* results in samples collected by FSIS at their New Jersey, Florida, and Texas facilities. You were unable to provide evidence you performed a reassessment of your HACCP system regarding *Listeria* controls considering this information as required by 9 CFR 417.4(b)(4). Based on this information you have not supported a decision that (b)(4) (b)(4) as required by 9 CFR 417.5(a)(1). You selected (b)(4) (b)(4). Please note that freezing will only limit or suppress the growth of *Lm* if the product remains frozen throughout the distribution and shelf life of the product. Your customers routinely thaw your products to produce RTE products that are shipped and maintained in a fresh, not frozen, state throughout the shelf life of their products. This results in a determination that your HACCP system is not validated as required by 9 CFR 417.4.

Conclusion

A HACCP system should be designed to identify, evaluate, and control hazards which are considered significant, relative to food safety and public health. The focus should be on the prevention of food safety hazards to ensure the resulting products are safe and will not cause illness or harm to the consumers of those products as required by the FMIA and PPIA. Failure to produce products in this manner may result in products potentially injurious to health. Based on the findings described within the preceding paragraph(s), FSIS has determined that continued production of products within your Fully Cooked Not Shelf Stable HACCP process may result in their adulteration. In summary, your establishment has failed to effectively maintain sanitary conditions as required in 21 U.S.C. 456 Section 7, of the PPIA based on the lack of effective food safety process controls as required in 9 CFR Part 416, 417 and Part 430 *et. seq.* Conditions in your establishment are such that product can become adulterated as defined by 21 U.S.C. 453, Section 4(g)(1 and 4) of the PPIA which state that the term adulterated may be applied to a product *"If it bears or contains any poisonous or deleterious substances which may render it injurious to health..."* and *"...if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health."*

In accordance with 9 CFR Part 500.3(a)(1) and (4), FSIS is exercising authority to withhold the federal marks of inspection and suspend the assignment of inspection program personnel (IPP) at your establishment. The withholding of the federal mark of inspection and suspension of the assignment of IPP will remain in effect for all HACCP categories at your establishment until you provide adequate written corrective action and preventative measures to demonstrate adherence to regulatory requirements. You may submit your corrective and preventive actions to my attention at the Dallas District Office.

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 contaminated 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:

Ms. Sherri Johnson
Executive Associate for Regulatory Operations
Office of Field Operations
Food Safety and Inspection Service, USDA
1400 Independence Avenue, SW
Room 3164, South Building
Washington, DC. 20250
Mobile: (b)(6)
Sherri.Johnson@usda.gov

BrucePac
Notice of Suspension
October 9, 2024

4

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:

Mr. 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 me at (214) 906-6758 or Jennifer.mckean@usda.gov. Additionally, you may contact Mr. (b)(6) Supervisory Enforcement Investigations Analysis Officer at (b)(6) or (b)(6) [@usda.gov](mailto:(b)(6)@usda.gov).

Sincerely,

JENNIFER
BEASLEY
MCKEAN

Digitally signed by JENNIFER BEASLEY
MCKEAN
DN: c=US, o=U.S. Government,
ou=Department of Agriculture,
0.9.2342.19200300.100.1.1=1200100000
3383, cn=JENNIFER BEASLEY MCKEAN
Date: 2024.10.09 11:04:47 -05'00'

Jennifer Beasley-McKean, DVM
District Manager

cc:

Dr. (b)(6) Frontline Supervisor, Oklahoma, OK
Inspector in Charge, Establishment 51205/P-51205, Durant, OK



October 9, 2024

BrucePac
Establishment 51205/P-51205
1915 Business 70
Durant, OK 74701

Sent via email and USPS

Attention: Mr. Robert Bruce, Owner

REVISED NOTICE 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 BrucePac, Establishment 51205/P-51205, located at 1915 Business 70, Durant, Oklahoma. This letter follows the verbal notification of the suspension action, provided by Dr. Jennifer Beasley-McKean, District Manager, to you at approximately 2:00 p.m. on October 8, 2024. This action includes all Fully Cooked, Not Shelf Stable Hazard Analysis Critical Control Point (HACCP) processes employed by your establishment.

The decision to institute this enforcement action is in accordance with Rules of Practice, Title 9 of the Code Federal Regulations (CFR) Part 500.3(a)(1) and (4) based on the determination that your establishment shipped adulterated product as defined in 21 U.S.C. 602 and that sanitary conditions are such that products in the establishment are or would be rendered adulterated.

Background/Authority

The Federal Meat Inspection Act (FMIA), 21 United States Code (USC) Section 601 (et. seq.), and The Poultry Products Inspection Act (PPIA), 21 USC 451 (et. seq.), provide 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 Acts give 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. These Acts provide 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 the Acts, 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

Food Safety and Inspection Service
Office of Field Operations
Dallas District Office
1100 Commerce Street, Room 516
Dallas, TX 75242
Voice 214-767-9116 Fax 844-622-0080
An Equal Opportunity Provider and Employer

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

FSIS collected samples of ready-to-eat (RTE) products produced at Taylor Farms, Est. 44818/P-44818 on September 10, 2024. This sample confirmed positive for *Listeria monocytogenes* (Lm) on September 19, 2024. FSIS collected a sample of RTE product produced at Taylor Farms, Est. 34513A/P-34514A on September 24, 2024. This sample confirmed positive for Lm on October 1, 2024. FSIS collected a sample of RTE product produced at Taylor Farms Texas, LLC, Est. 34733/P-34733 on September 25, 2024. This sample confirmed positive for Lm on September 30, 2024. FSIS also submitted 5 unopened boxes of Grilled Chili Lime Seasoned Diced Chicken produced on September 12, 2024, for laboratory analysis. This product was shipped to Taylor Farms Est. 34733/P-34733 and was used to make the salad that was sampled by FSIS on September 25, 2024. The unopened 35-lb boxes produced by your establishment were submitted to the laboratory on October 4, 2024. On October 8, 2024, the samples were determined to be presumptive positive for Lm. Additionally on October 8, 2024, FSIS determined that the three Lm isolates from the samples collected at the three Taylor Farms establishments are closely related (within 7 alleles) by Whole Genome Sequencing (WGS). This evidence indicates the source of Lm originated at your establishment, and not at your customers' establishments.

There is compelling evidence that corrective actions your establishment took in response to the (b)(4) product samples that you collected which were produced (b)(4) (b)(4) have been ineffective. You performed intensified cleaning and sanitation and collected additional samples of food contact surfaces and the environment between (b)(4) (b)(4). You also reassessed your Fully Cooked Not Shelf Stable HACCP plan on August 13, 2024. However, product produced on September 12, 2024, was still confirmed to be adulterated with Lm. You received notification from Taylor Farms of the positive Lm results in samples collected by FSIS at their New Jersey, Florida, and Texas facilities. You were unable to provide evidence you performed a reassessment of your HACCP system regarding *Listeria* controls considering this information as required by 9 CFR 417.4(b)(4). Based on this information you have not supported a decision that (b)(4) (b)(4) as required by 9 CFR 417.5(a)(1). You selected (b)(4) Please note that freezing will only limit or suppress the growth of Lm if the product remains frozen throughout the distribution and shelf life of the product. Your customers routinely thaw your products to produce RTE products that are shipped and maintained in a fresh, not frozen, state throughout the shelf life of their products. This results in a determination that your HACCP system is not validated as required by 9 CFR 417.4.

Conclusion

A HACCP system should be designed to identify, evaluate, and control hazards which are considered significant, relative to food safety and public health. The focus should be on the prevention of food safety hazards to ensure the resulting products are safe and will not cause illness or harm to the consumers of those products as required by the FMIA and PPIA. Failure to produce products in this manner may result in products potentially injurious to health. Based on the findings described within the preceding paragraph(s), FSIS has determined that continued production of products within your Fully Cooked Not Shelf Stable HACCP process may result in their adulteration. In summary, your establishment has failed to effectively maintain sanitary conditions as required in 21 U.S.C. 456 Section 7, of the PPIA based on the lack of effective food safety process controls as required in 9 CFR Part 416, 417 and Part 430 *et. seq.* Conditions in your establishment are such that product can become adulterated as defined by 21 U.S.C. 453, Section 4(g)(1 and 4) of the PPIA which state that the term adulterated may be applied to a product *"If it bears or contains any poisonous or deleterious substances which may render it injurious to health..."* and *"...if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health."*

In accordance with 9 CFR Part 500.3(a)(1) and (4), FSIS is exercising authority to withhold the federal marks of inspection and suspend the assignment of inspection program personnel (IPP) at your establishment. The withholding of the federal mark of inspection and suspension of the assignment of IPP will remain in effect for all HACCP categories at your establishment until you provide adequate written corrective action and preventative measures to demonstrate adherence to regulatory requirements. You may submit your corrective and preventive actions to my attention at the Dallas District Office.

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 contaminated 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:

Ms. Sherri Johnson
Executive Associate for Regulatory Operations
Office of Field Operations
Food Safety and Inspection Service, USDA
1400 Independence Avenue, SW
Room 3164, South Building
Washington, DC. 20250
Mobile: (b)(6)
Sherri.Johnson@usda.gov

BrucePac
Notice of Suspension
October 9, 2024

4

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:

Mr. 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 me at (214) 906-6758 or Jennifer.mckean@usda.gov. Additionally, you may contact Mr. (b)(6) Supervisory Enforcement Investigations Analysis Officer at (b)(6) or (b)(6) [@usda.gov](mailto:(b)(6)@usda.gov).

Sincerely,

JENNIFER
BEASLEY
MCKEAN

Digitally signed by JENNIFER BEASLEY
MCKEAN
DN: c=US, o=U.S. Government,
ou=Department of Agriculture,
o.9.2342.19200300.100.1.1=1200100006
3383, cn=JENNIFER BEASLEY MCKEAN
Date: 2024.10.09 14:37:58 -05'00'

Jennifer Beasley-McKean, DVM
District Manager

cc:

Dr. (b)(6) Frontline Supervisor, Oklahoma, OK
Inspector in Charge, Establishment 51205/P-51205, Durant, OK