



Food Safety and
Inspection Service

Alameda District
620 Central Avenue,
Bldg. 2C
Alameda, CA 94501

Phone: (510) 769-5712
Fax: (510) 337-5081

October 7, 2013

Mr. Ron Foster, CEO
Zorro Leasing, LLC
dba Foster Farms
Establishment 7632 P
900 West Belgravia
Fresno, CA 93706

**CERTIFIED RETURN-
RECEIPT REQUESTED**

Email: Robert.Oconner@fosterfarms.com

NOTICE OF INTENDED ENFORCEMENT

Dear Mr. Foster:

This letter serves as an official notification by the Food Safety and Inspection Service (FSIS), Alameda District, of the intent to withhold the marks of inspection and suspend the assignment of inspectors for the Slaughter, Raw Intact and Raw Non Intact processes at your establishment, in accordance with FSIS Rules of Practice, Title 9 Code of Federal Regulations (CFR) Parts 500.4(a), 500.4(b) and 500.4(c). This action is based on your establishment's failure to operate in a manner that is consistent with the requirements of the Hazard Analysis and Critical Control Points (HACCP) plan, Sanitation Standard Operating Procedures (SSOP) program, and Sanitation Performance Standards (SPS) regulations, Title 9 Parts 417 and 416. Your failure to operate in accordance with these regulations at Establishment 7632 in Fresno, California, is evidenced by the fact that multiple poultry products produced by your establishment have been implicated in an ongoing illness outbreak for *Salmonella* Heidelberg. Since July 1, 2013, FSIS and the Centers for Disease Control and Prevention (CDC) have been investigating an ongoing outbreak of human illness caused by *Salmonella* Heidelberg beginning in March 2013, through at least September 2013. In addition, your failure to operate in accordance with the abovementioned regulations is evidenced by the results of intensified *Salmonella* verification testing conducted by FSIS over a three week period in September 2013. This intensified testing occurred at multiple Foster Farms establishments, including Establishment 7632, whereby a high frequency of *Salmonella* positives and, specifically, a high frequency of one or more outbreak strains of serotype *Salmonella* Heidelberg were found in your products.

Background/Authority

The Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) provides that it is essential in the public interest that the health and welfare of consumers be protected, by ensuring that poultry and meat products distributed to them are wholesome, not adulterated, and properly marked, labeled and packaged. The Act gives FSIS the authority, as delegated by the Secretary of the Department of Agriculture, to prescribe rules and regulations describing sanitation requirements for inspected establishments. The Act also provides FSIS program personnel the authority to refuse to allow poultry or poultry food products and meat or meat food products to be labeled, marked, stamped, or

tagged as '*inspected and passed*' and to prevent the entry of products into commerce when the sanitary conditions of any such establishment are such that product is rendered adulterated, and provide definitions for the term '*adulterated*.' Furthermore, the Act provides FSIS the authority to appoint inspectors from time to time to examine and inspect products, including the sanitary conditions of facilities. The Act also gives FSIS program personnel the right to examine and inspect all carcasses and parts of carcasses that are further treated and prepared and the right to access and examine establishment records. When a facility does not properly maintain sanitary conditions, FSIS can refuse to provide inspection and indefinitely suspend inspection from an establishment provided that FSIS affords the establishment appropriate notice and an opportunity to contest the suspension.

Under the authorities of the Act, FSIS has prescribed rules and regulations required for establishments producing poultry products including the requirements pertaining to Sanitation Standard Operating Procedures (Title 9 CFR Part 416) and Hazard Analysis and Critical Control Point (Title 9 CFR Part 417) and other matters. FSIS has also developed Rules of Practice regarding enforcement (Title 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 suspension, with or without prior notification, and for filing a complaint to withdraw a grant of Federal inspection.

Findings/Basis for Action

On July 1, 2013, FSIS was notified of a *Salmonella* Heidelberg cluster with Pulse Field Gel Electrophoresis (PFGE) pattern JF6X01.0258. Since that time CDC, has defined the outbreak to include six additional patterns (.0022, .0045, .0041, .0326, .0122 and .0672) as part of the case outbreak definition. As of September 30, 2013, there are 207 case-patients from 15 states with illness onset dates range from March 2, 2013, to September 9, 2013. The majority of case-patients reported chicken consumption prior to illness onset; among those with brand information, 80 % reported consumption of Foster Farms chicken during case-patients' interviews. A high proportion of case-patients were hospitalized. Foster Farms has been implicated as the producer and supplier of poultry products associated with an ongoing *Salmonella* Heidelberg illness outbreak in several states.

Establishment 7632 has been implicated as a producer and supplier of poultry products associated with this ongoing *Salmonella* Heidelberg illness outbreak. As a result, on September 9, 2013, FSIS initiated intensified *Salmonella* verification testing of various poultry products at this establishment, as well as three other Foster Farms establishments (Establishment 6137 in Livingston, California; Establishment 6137A in Fresno, California; and Establishment 6164A in Kelso, Washington).

Results from the intensified FSIS *Salmonella* verification testing, have shown that one or more of the outbreak strains of *Salmonella* was found in the poultry products produced at your facility. Additionally, the results have shown that one or more of the outbreak strains of *Salmonella* Heidelberg is present in your products. Ongoing illness continues to be associated with these products. FSIS personnel collected 150 various product samples

at Establishment 7632. As of October 7, 2013, a total of 37 samples (24.67 %) confirmed positive for *Salmonella*. There have been 33 isolates of *Salmonella* Heidelberg derived from the *Salmonella* positive samples thus far (See Attachment 1). Furthermore, FSIS has found that multiple *Salmonella* isolates identified on products produced at your facility have the same PFGE patterns as those in the illness outbreak. Although presence of the outbreak strain alone is not evidence that product is adulterated, presence on product coupled with illnesses suggests that the sanitary conditions in the establishment under which the product is produced could pose a serious ongoing threat to public health. The frequency of microbiologically-relevant positive findings suggests that the slaughter, dressing, and further processing of raw poultry product, including the prevention of contamination and the pathogen reduction interventions, are inconsistent and unreliable to control the pathogen of concern. Your sister facility, Establishment 6164A, in Kelso, Washington, was also under intensified FSIS *Salmonella* verification testing. However, Establishment 6164A demonstrated a more consistent and effective process control based on the results of the microbiological testing, along with less evidence of illnesses being associated with product from this establishment. The samples collected from Establishment 6164A resulted in a 1.3% (2/150 samples) *Salmonella* positive rate with only one of the positive samples being associated with the *Salmonella* Heidelberg outbreak strain.

Pathogens such as *Salmonella* are of serious public health concern and can cause a variety of illnesses. The organism can cause a serious infection which can lead to illnesses, including death. Your establishment has failed to demonstrate that it has adequate controls in place to address *Salmonella* in your poultry products as evidenced by the continuing illness outbreak. Your establishment's control measures and antimicrobial interventions in your Slaughter, Raw Intact and Raw Non Intact operations are not sufficient to control *Salmonella*, specifically, *Salmonella* Heidelberg, which has been associated with the illness outbreak. This is a regulatory noncompliance with Title 9 CFR 417.4(a)(1).

Your establishment identifies *Salmonella* as a food safety hazard not reasonably likely to occur in your Raw Intact and Raw Non Intact processes. However, as evidenced by the multiple *Salmonella* positive test results in poultry parts and whole chickens produced at your facility, your establishment is unable to support that *Salmonella* is a biological food safety hazard not reasonably likely to occur in your Raw Intact and Raw Non Intact processes. Your establishment has failed to implement adequate control measures to address the prevalence of *Salmonella* in your poultry products. Your establishment is unable to support the decisions in your Raw Intact and Raw Non Intact hazard analyses. This is a regulatory noncompliance with Title 9 CFR 417.2(a), as well as the associated requirements of Title 9 CFR 417.5(a)(1).

Foster Farms was notified on July 25, 2013, via teleconference with Foster Farms Corporate officials and FSIS management personnel, of the ongoing illness outbreak associated with Foster Farms poultry products, including a specific identification of Establishment 7632. Your establishment failed to adequately reassess the HACCP plan

and modify the plan to control food safety hazards that could be introduced inside or outside the establishment. This is noncompliant with Title 9 CFR 417.4(a)(3).

Although FSIS is primarily concerned with the performance of the establishment beginning at the time of the intensified FSIS *Salmonella* testing and forward, the performance of the establishment just prior to and during the time of the illness onset forward also is of concern. During this time, your establishment has had multiple regulatory noncompliances issued for insanitary conditions. Specifically, from January 1, 2013, (just prior to identification of illness in early March), through September 27, 2013, FSIS personnel have documented 10 Noncompliance Records (NRs) for findings of fecal material on carcasses. Furthermore, FSIS has identified multiple noncompliances including but not limited to findings of poor sanitary dressing practices, insanitary food contact surfaces, insanitary non food contact surfaces and direct product contamination as evidenced by the documentation of a considerable number of recurring NRs issued to your establishment for preoperational, operational, and SPS noncompliances.

For the reasons stated above and in accordance with Title 9 CFR 417.6(a) and Title 9 CFR 417.6(d), FSIS has determined your HACCP system is inadequate. Additionally, the multiple and recurring sanitation noncompliances identified at your facility during the period of time your establishment was implicated with associated illnesses, could indicate your establishment has failed to operate and produce poultry products in a manner that complies with Title 9 CFR 416.1.

FSIS is very concerned with the failure of Establishment 7632 to implement adequate and supportable control measures to address *Salmonella*, coupled with the high frequency of one or more outbreak strains of *Salmonella* Heidelberg associated with ongoing illnesses and found in products produced by this establishment. You are unable to effectively implement and maintain your HACCP system or demonstrate that your establishment's process controls are functioning as intended to prevent or control *Salmonella* in your process. The prevalence of *Salmonella* in finished poultry products poses a risk to public health. As demonstrated by the FSIS *Salmonella* verification testing, your establishment has failed to prevent the production of products contaminated with *Salmonella* and of a serotype known to cause human illness.

A prudent establishment would take the control measures necessary to prevent the persistent recurrence of *Salmonella*, including but not limited to validated interventions to demonstrate control of your process. FSIS affirms that proper process controls are an important, fundamental, and integral aspect of an adequate food safety system.

The Poultry Products Inspection Act, 21 U.S.C. 456 states: "*the Secretary shall refuse to render inspection to any establishment whose premises, facilities, or equipment, or the operation thereof, fail to meet the requirements of this section.*" Zorro Leasing, LLC, dba Foster Farms, failed to implement and maintain an adequate HACCP system. This resulted in the failure to maintain sanitary conditions at the establishment that could result in the production of products that may have been rendered injurious to health.

In accordance with FSIS Rules of Practice, Title 9 CFR Part 500.4, we are notifying you of our intent to withhold the marks of inspection and suspend the assignment of inspectors at your facility. You are required to respond this notice adequately, in writing, addressing all regulatory non-compliances in this notice. Please provide this office with a written response within three (3) business days from the date of your receipt of this letter. We will determine if any further administrative enforcement action will be taken based on your response. You may submit your response by facsimile to (510) 337-5081.

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

Dr. Keith Gilmore
Executive Associate for Regulatory Operations
210 Walnut Street
Room 923
Des Moines, IA 50309
Phone: 515-727-8970

If you have any questions, please call the Alameda District Office at (510) 769-5712.

Sincerely,



Yudhbir Sharma, DVM
District Manager

cc:

Y. Sharma, DM
F. Gillis, DDM
A. Amin, DDM
V. Felix, DDM
L. Wang, DCS
J. Scrivner, DCS
A. Darwish, FLS
M. Tiojanco, SEIAO
C. Vu, SEIAO
R. Flood, EIAO
M. Salazar, EIAO
A. Khroustalev, IEA, RD
USDA IIC, Est. 7632P
FO/QR