

**UNITED STATES DEPARTMENT OF AGRICULTURE
BEFORE THE SECRETARY OF AGRICULTURE**

In re:) **FMIA Docket No. 03-0007**
) **PPIA Docket No. 03-0004**
HOMESTEAD GOURMET FOODS, INC.,)
)
Respondent)

ORDER

A. Procedural History

This is a proceeding brought by the Complainant Secretary of Agriculture (USDA) against Respondent Homestead Gourmet Foods, Inc. (Homestead) under the Federal Meat Inspection Act, as amended (21 U.S.C. Sec. 601 *et seq.*), (“FMIA”), the Poultry Product Inspection Act, as amended (21 U.S.C. Sec. 451 *et seq.*) (“PPIA”), and the applicable rules and regulations promulgated pursuant to the Acts. The Rules are titled the Regulatory Requirements Under the Meat Inspection Act and the Poultry Products Inspection Act and are found at (9 C.F.R., Sec., 416.1 *et seq.*; Sec. 417.1 *et seq.*); and the Rules of Practice (9 C.F.R. Sec. 500.1 *et seq.*). Generally, each official establishment (such as Homestead) must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated (9 C.F.R. Sec. 416.1). Each official establishment shall also develop, implement and maintain written standard operating procedures for sanitation (SSOP’s), (9 C.F.R. Sec. 416.11). Additionally, every establishment shall develop and implement a written Hazard Analysis and Critical Control Point System (HACCP) plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur (9 C.F.R. Sec. 417.2 (a), (b)).

This proceeding was commenced by a complaint filed before the Secretary of Agriculture (USDA) on September 24, 2003, by the Administrator of the Food Safety and Inspection Service (FSIS), which is responsible for the administration of federal meat inspection and poultry product inspection services. Rules and regulations promulgated pursuant to the “continuous inspection” requirements of Sec. 8 of FMIA and Sec. 7 of PPIA provide for daily and shift inspection of meat products at plants like Homestead. Federal food inspection services were withdrawn from Homestead pursuant to the above statutes and regulations.

Homestead answered the complaint on October 14, 2003, and filed the instant expedited Motion for Reinstatement of Inspection Services Pending Hearing on November 14, 2003. Complainant responded on December 4, 2003. A hearing was held in Washington, D.C. on December 11, 2003. Carlynne S. Cockrum and Tracey Manoff represented the Secretary of Agriculture. Robert G. Hibbert represented Homestead. Counsel for the parties agreed that the hearing was procedurally interlocutory and injunctive in nature.

Homestead claimed that the statute and rules were being applied to it in an arbitrary and capricious manner. It claimed that its status as an ongoing business with a payroll was irreparably harmed by Complainant's actions and that it would continue to suffer absent injunctive relief. It claimed that it was reasonably likely to prevail on the merits and that a comparison of the hardship to it if relief were denied outweighed the government's ability to protect the public with the tools the government has at its disposal. Additionally, it stated that it was not seeking poultry inspection services.

The USDA responded that it is charged by Congress with the responsibility to prevent "adulterated" food from reaching the market and that a facility that appears "clean" may not, in fact, be clean. The USDA stated that it had not received plans that assured FSIS that reinstatement of inspection services was warranted and that Homestead has not demonstrated that it was ready for reinspection services. It claimed that Homestead had provided a consistent record of an inability to comply, and no demonstrated willingness to comply with the Regulations. USDA indicated that because of the numerous notices and suspensions of Homestead that it had "little confidence" that Homestead was ready to comply.

B. Factual History

Homestead: Zalman Sandon, the Vice President of Homestead, testified that Homestead was first granted USDA inspection in 1979. Homestead's primary business is processing delicatessen meat products such as pastrami, corned beef, roast beef and smoked turkey. The company has annual sales in excess of 21 million Dollars and employs 22 people in production.

He testified that he was not working at Homestead on prior occasions when the company was suspended or had inspection services withheld. He testified that at one point in time, Homestead produced smoked turkey breast that was not covered by a HACCP. Upon developing a HACCP for turkey breast, production resumed.

He testified that he had received training in SSOP and HACCP development and that Homestead retained outside safety experts to help achieve compliance with USDA Regulations.

He further testified that Homestead made recent changes to its SSOP and HACCP in order to comply with USDA suggestions. Specifically, he testified that Homestead had improved and eliminated condensation in food preparation areas, had undertaken physical improvements by "essentially rebuilding the plant", that it had improved airflow and that its ovens were in good working order and that it was moving one of the ovens per USDA request. Exhibits reflect that changes to the SSOP and HACCP were occurring even up to the weeks prior to the hearing (RX 1 and RX2).

He acknowledged deficiencies in the plant in June 2003 but insisted that the problems had been corrected. He testified that an August 2003 positive finding of *Lysteria monocytogenes* in one sample taken from a small drop of water on the floor was not of sufficient magnitude to suspend inspection.

He said that the current business status of Homestead was dire, that the suspension of inspection “impacted (the business) like a ton of bricks”. He testified that its resources are being sapped, that it had lost employees and customers. The company’s savings and goodwill were nearly lost and that only reinstatement of inspection services would allow the company to survive. He said that he understood the risk of a finding of further non-compliance but that he would do all he could to meet USDA objections. He claimed that they had always been producers of sanitary products.

United States Department of Agriculture: Jan Behney, FSIS District Manager of the Philadelphia office, testified that Homestead was a plant that came under his jurisdiction in June 2002. He characterized Homestead as a troubled plant after he reviewed records that were originally maintained in Albany, NY. He personally visited the plant with the Deputy District Manager and an inspector. Based on his review of the records, his visit to the plant and his personal assessment of the situation, he assigned Joseph Realdine to perform a comprehensive inspection at the Homestead plant in June 2003. When he received the results of the more than week-long inspection of the Homestead plant, he noted that the SSOP and HACCP plans were deficient, that Homestead was not in compliance with its own plan, that there was a lack of record keeping and that there was a positive test for *Lysteria monocytogenes*. In early July 2003 he issued a Notice of Suspension of Inspection Services as a result of the comprehensive inspection (CX 2). After back and forth negotiations between Homestead and USDA, the Suspension of Inspection Services order was held in abeyance and the plant reopened after August 21, 2003 (CX-3). Within weeks of the suspension being held in abeyance, new non-compliance reports were filed reflecting condensation, undercooking and, most significantly, another positive finding of *Lysteria monocytogenes*. He reinstated the suspension of inspection on September 19, 2003 (CX-4).

He acknowledged that USDA inspectors have vast authority in the field and that they can rapidly respond to dangers in the operating establishments under their control. He testified that despite USDA inspection authority, Homestead did not have the commitment to execute and maintain compliance with the rules and regulations. He said that he has no confidence that the public interest in being assured that adulterated food is not entered into commerce could be assured by reinstating inspection to Homestead.

Joseph Realdine, then a consumer safety officer and now a Regional Supervisor of Inspectors, testified that he was directed to perform a food safety inspection at Homestead in June 2003. He sought authority to perform an intensive test of the Homestead plant. He specifically wanted to test for *Lysteria monocytogenes* because he regarded the plant to be at high risk. As part of the inspection, a wooden partition between the raw meat area and the cooking area of the plant was tested. Upon applying pressure to the wall, the wood broke away and a worm came out of the hole in the wall. The sample collected from the rotted wood area

was positive for *Lysteria monocytogenes*. As a result of the testing, inspection services at the plant were suspended.

He returned in September 2003, after the plant was allowed to reopen, and performed a second intensive inspection. Once again a positive test for *Lysteria monocytogenes* occurred. Additionally, he testified that one of the ovens produced a product that was too cool and that the condensation problem had not been cured.

Dr. Gerald Zirnstein, a food microbiologist, was called as an expert witness. He testified to the dangers of *Lysteria monocytogenes* and expressed concern that *Lysteria monocytogenes* was found in both the raw food area and the area where cooking occurred. His opinions were that due to inconsistent cooking temperatures in the processing area, there was a significant danger of *Lysteria monocytogenes* contamination and adulteration of the meat product and hence transfer to humans. He testified that Homestead appeared unable to control the presence of the microbe in its plant.

C. Findings and Conclusions

Pursuant to the Federal Meat Inspection Act, as amended (21 U.S.C. Sec. 601 *et seq.*), (“FMIA”), and the Poultry Product Inspection Act, as amended (21 U.S.C. Sec. 451 *et seq.*) (“PPIA”), USDA promulgated rules and regulations. They are the Regulatory Requirements Under the Meat Inspection Act and the Poultry Products Inspection Act (9 C.F.R., Sec., 416.1 *et seq.*; Sec. 417.1 *et seq.*); and the Rules of Practice (9 C.F.R. Sec. 500.1 *et seq.*). Under the Administrative Procedure Act, an agency decision may be set aside if it is “arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law”, 5 U.S.C. Sec. 706(2)(A). In order to be arbitrary and capricious, there must be a clear indication that an agency determination “relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem or offered an explanation for its decision that runs counter to the evidence before the agency or is so implausible that could not be ascribed to a difference of view or the product of agency expertise”. See, Greenville Packing Co. Inc., 60 Agric. Dec. 517, (2001), *citations omitted*.

USDA did not act in an arbitrary or capricious manner in this case. There was a long history of problems at Homestead prior to the transfer of jurisdiction over the plant to the Philadelphia District Office. An inspection conducted in June 2003 revealed that a wooden partition between work areas of the plant was rotten. Pressure applied to a portion of the partition produced a live worm. The rotted wood tested positive for *Lysteria monocytogenes*, a known microbiotic pathogen. Additionally, food preparation produced condensation that held the potential to contaminate food products. There was uneven cooking of food products and misplacement of cooking ovens. The decision to suspend inspection services is well within agency expertise.

In passing the FMIA and the PPIA, Congress identified the public interest in being assured that meat products were not adulterated. The public interest is vastly superior to the

interest a business has in regulating itself. In providing for “continuous inspection”, the USDA is charged by Congress to make that assurance a reality. In carrying out its duty under the Acts, USDA has expressly relied on factors that Congress has ordered it to consider. In fulfilling its mission, USDA has considered every important aspect of the problem of meat contamination at operating establishments and has offered an explanation for its decision that is fully consistent with the evidence before the agency.

Homestead has not made a showing of irreparable harm. It retains the ability to persuade the USDA that it is capable of executing and maintaining compliance with the regulations. Indeed, this hearing is an example of the due process protections provided to Homestead in its efforts to persuade the USDA that it is capable of executing and maintaining compliance with the regulations. Further, as a twenty-five year old plant, it can fully renovate its plant or obtain a new site and construct a brand new state-of-the-art plant and apply for inspection. At this stage of the proceeding, an injunction is not the only avenue of relief that Homestead can undertake to obtain inspection services.

Homestead’s likelihood of success on the merits is diminished in light of its failure to pass two inspections conducted within three months of each other. The finding of *Lysteria monocytogenes* in a wooden partition and a subsequent finding of *Lysteria monocytogenes* in a drop of water on the floor in front of an oven where cooked product is handled reflects an unlikelihood of success on the merits.

By any measure, Congress’ express determination to assure that only unadulterated food products reach the consuming public is an interest that vastly outweighs Homestead’s desire to continue producing food that is at significant risk of producing adulterated meat.

IT IS THEREFORE ORDERED that the Motion for Reinstatement of Inspection Services Pending Hearing is **DENIED**, and it is further;

ORDERED that all other orders entered in this matter remain in effect including the scheduling order.

SO ORDERED this _____ day of December, 2003.

LESLIE B. HOLT
Administrative Law Judge

Hearing Clerk’s Office
U.S. Department of Agriculture
1400 Independence Ave., SW
Room #1081, South Building
Washington, D.C. 20250-9200
202-720-4443
Fax: 202 720 9776