

Food Safety, Quality and Food Defense Audit

Company Information	Audit Information
Facility: C0193771 - MacFarlane Pheasant Inc Address: 2821 South US Hwy 51 Janesville, Wisconsin United States, 53546 Contact: Sarah Baker Title: Phone: 608-314-3450 Fax: Email: s.baker@pheasant.com	Audit# - Visit#: 1257848 - 964126 Audit Type: B1WMT - Food Safety, Quality and Food Defense Audit Template Version: 1.4 Audit Category: REGULAR Auditor: Daniel Uthe Audit Start Time: 22-MAR-2016 07:55:00 AM Audit End Time: 22-MAR-2016 01:30:00 PM Prior Audit Date: 04-MAR-15

Explanation of Section Scorings (below)

Section scorings in the below table are provided as a reference and are calculated on the following formula:

Non-Conformance	Deduction of 5% per finding
Major Non-Conformance	Deduction of 25% per finding
Critical	0%

Summary By Section				
Section Name	Non-Conformance	Major Non-Conformance	Critical	Score
Section A - ADMINISTRATION & REGULATORY COMPLIANCE	0	0	0	100.00%
Section B - HACCP	0	0	0	100.00%
Section C - FACILITIES & EQUIPMENT (The Manufacturing Environmental Controls Prerequisite System)	1	0	0	95.00%
Section D - SANITATION, HOUSEKEEPING & HYGIENE	1	0	0	95.00%
Section E - RODENT & PEST CONTROL MANAGEMENT	1	0	0	95.00%
Section F - APPROVED SUPPLIERS, RECEIVING, STORAGE& SHIPPING& INVENTORY CONTROL	0	0	0	100.00%
Section G - PROCESS & PRODUCT EVALUATION	0	0	0	100.00%
Section H - FOREIGN MATERIAL CONTROL	0	0	0	100.00%
Section I - CHEMICAL CONTROL	0	0	0	100.00%
Section J - PACKAGING & LABELING	0	0	0	100.00%
Section K - TRAINING REQUIREMENTS	0	0	0	100.00%
Section L - LABORATORY SUPPORT	0	0	0	100.00%
Section M - FOOD DEFENSE	0	0	0	100.00%
Section N - READY TO EAT (RTE) FOODS PROCESSING REQUIREMENTS	0	0	0	100.00%

Explanation of Overall Audit Result (below)

The overall score result is based on the total number and level of non-conformances. The audit is allocated 100% and deductions made as follows:

Non-Conformance = 1% deduction per finding off the total score
Major Non-conformance = 10% deduction per finding off the total score
Critical Non-conformance = 25% deduction per finding off the total score

Scoring Guide	
Final Audit Rating	Based on Score
Meets Expectations	100-95%
Needs Improvement	94.99-85%
Significant Improvement Needed	84.99-76%
Fail	≤ 75.99%

Overall Audit Result	
Grade Rule Result	% Score
Meets Expectations	97.00%

Present at Audit					
Name	Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Ryan George	Food Products Business Manager	Yes	Yes	Yes	Yes
Terry Eytalas	Cut Room Supervisor	Yes	Yes	Yes	No

GENERAL INFORMATION	
No	Question/Notes
1	Provide a Company Profile. (Include a description of the surroundings, buildings, size, construction, number of personnel, lines, and shift, operational description/ nature of the operation/ major processes).
2	<p>Check from the predefined notes and/or if not listed in the predefined notes document all of the Animal Protein HACCP Categories covered by the scope of audit. Please ensure that you document all HACCP plans that are currently operational for which the facility is manufacturing product:</p> <p>Raw, Not Ground Meat and Poultry Products</p> <p>They have 2 CCPs for their Raw Not Ground HACCP category. Both are for biological controls. During packaging and labeling they maintain product temperature of 41 degrees F or less but do allow for a temporary temperature rise to 50 degrees but must cool back to 41 degrees within 8 hours. This CCP covers whole birds and parts. Documentation was available supporting both CCPs.</p> <p>The second CCP is for thawing and cutting with the same critical limits. The facility rarely thaws frozen pheasants but have considered the possibility.</p> <p>Test information from notes section of question. Lorem ipsum dolor sit amet, consectetur adipiscing elit. Phasellus mi dolor, dictum non placerat non, dictum ut justo. Morbi nec elementum purus. Phasellus elit elit, laoreet sed sapien a, elementum gravida ex. Proin vel urna tincidunt, aliquet eros pellentesque, eleifend augue. Phasellus et justo dui. Proin non sollicitudin felis. Phasellus posuere ullamcorper mi sit amet euismod. Pellentesque scelerisque rutrum nibh at dapibus. Nulla facilisi.</p> <p>Vestibulum tincidunt gravida dolor eu pellentesque. Nulla vitae sodales risus. Duis mi leo, egestas ut quam eu, efficitur eleifend ante. Suspendisse consequat nisl dolor, vel tempor dui consectetur vel. Donec sed ultricies turpis. In hac habitasse platea dictumst. Sed lacinia metus urna, a egestas ante maximus ac. Suspendisse tristique magna quis arcu rhoncus, at dignissim nunc vehicula. In velit risus, faucibus eu pellentesque ac, porta et ante</p>

Non-Compliance Summary		
No	Question/Notes	Result
Section C/ C3.1	<p>Plant facilities shall be designed and maintained in an orderly, clean condition so as not to impede the ability to thoroughly clean all surfaces, provide pest harborage, or present opportunities for foreign material contamination.</p> <p><i>There was a small amount of damage near the door of the freezer. There was a wall panel that was uneven and a small gap in the seam. The door to the cooler that was noted in the previous audit had been repaired.</i></p> <p><i>NC-The holding freezer had some minor damage near the door on the left side when entering.</i></p>	Non-conformance*
Section D/ D2.1	<p>The facility has a documented program for GMP and Personal Hygiene practices to which compliance is monitored and recorded.</p> <p><i>All employees were wearing head coverings that covered all hair on the head. The room was less than 40 degrees so many of the workers had stocking caps that completely covered the hair on their head. 3 individuals had short mustaches that were not covered because they were very short.</i></p> <p><i>NC-Fine mesh hair restraints were not being worn by all employees.</i></p>	Non-conformance*
Section E/E1.2	<p>Outside Premises Management shall minimize opportunity for pests</p> <p><i>The north side of the building has some cracks in the walkway and a fairly large crack between the walkway and the building that could provide pest harborage.</i></p> <p><i>NC-Pest harborage is possible on the north side of the building.</i></p>	Non-conformance*

Section A. ADMINISTRATION & REGULATORY COMPLIANCE		
No	Question/Notes	Result
A1.1	There must be a plant management organization chart indicating the reporting structure of the plant operating departments.	Acceptable
A1.2	There shall be implemented and documented policies and procedures that address relevant food safety, quality and security requirements for the receiving, handling, manufacturing and shipping of product.	Acceptable
A2.1	A file of regulatory visits and reports shall be maintained.	Acceptable
A3.1	There shall be a documented, current and implemented plant specific Recall Plan.	Acceptable
A3.2	Recall management responsibility shall be assigned.	Acceptable
A3.3	Traceability Exercises shall be conducted at least twice annually. An effective finished product traceability exercise is one where a finished product lot is traced to the first level of distribution taking into account normal yields, loss, waste or shrinkage. An effective raw material trace exercise is one where a received lot of raw material is traced to all the finished product it was used in and a mass balance calculation achieves 99.5-105% recovery, taking into account normal yields, loss, waste or shrinkage	Acceptable
A3.4	A documented management assessment shall be completed after each traceability exercise to evaluate the exercise for needed improvements and any corrective actions taken.	Acceptable
A3.5	ESSENTIAL There shall be evidence of traceability for all ingredients, rework, carryover, work in process, and food contact packaging materials into finished product. Finished product shipping records must be available.	Acceptable
A4.1	The facility shall have a record retention and storage policy.	Acceptable
A4.2	ESSENTIAL Records relevant to the control of the process or evaluation of food safety, food quality and food defense shall be properly completed.	Acceptable
A5.1	Crisis management policies and procedures shall be developed to address any critical situations that may occur, i.e. natural disasters and catastrophic events and other emergency situations (power outage, tampering, etc.)	Acceptable
A6.1	The plant shall manage customer and or consumer complaints.	Acceptable

Section B. HACCP		
No	Question/Notes	Result
B1.1	A HACCP team shall be assembled with individuals having the appropriate product, process, and sanitation specific knowledge and expertise necessary for the development of an effective HACCP plan. Where such expertise is not available on site, expert advice should be obtained from other sources.	Acceptable
B1.2	The HACCP team shall participate in HACCP program development and maintenance.	Acceptable
B1.3	The HACCP Team shall construct a clear and easy to understand process flow diagram for each HACCP plan. The same flow diagram may be used for a number of products that are manufactured using similar processing steps. The Process Flow Diagram shall include Critical Control Points (CCPs), shall be current and shall be verified.	Acceptable
B1.4	The Process Flow shall include CCPs, shall be current and shall be verified.	Acceptable
B2.1	The HACCP team shall prepare a list of all of the hazards (chemical, physical, biological or other) that may be reasonably expected to occur at each step, from raw material receipt, processing, manufacture, storage, and distribution until the point of consumption. Evaluation shall include all ingredients, equipment, processing steps, and packaging materials.	Acceptable
B3.1	The HACCP team shall determine the Critical Control Points.	Acceptable
B4.1	Critical limits shall be specified and validated for each CCP. Failure to demonstrate that CCP critical limits are scientifically and/or technologically sound for controlling each hazard shall be rated as a Major Nonconformance. Please document in the notes section all CCPs for each operational HACCP plan including critical limits. <i>They have 2 CCPs for their Raw Not Ground HACCP category. Both are for biological controls. During packaging and labeling they maintain product temperature of 41 degrees F or less but do allow for a temporary temperature rise to 50 degrees but must cool back to 41 degrees within 8 hours. This CCP covers whole birds and parts. Documentation was available supporting both CCPs.</i>	Acceptable

Section B. HACCP		
No	Question/Notes	Result
	<i>The second CCP is for thawing and cutting with the same critical limits. The facility rarely thaws frozen pheasants but have considered the possibility.</i>	
B5.1	CCPs shall be monitored.	Acceptable
B5.2	CCP monitoring records shall be maintained.	Acceptable
B6.1	ESSENTIAL Specific corrective actions to deal with deviations from established Critical Limits shall be in place for each CCP.	Acceptable
B7.1	There shall be verification documentation that confirms that the plan is being implemented as intended	Acceptable
B7.2	There shall be documented validation of the effectiveness of the HACCP program.	Acceptable
B8.1	There shall be Documentation and record keeping that is appropriate to the nature and size of the operation. It shall be sufficient to assist the business to verify that the HACCP controls are in place and being maintained	Acceptable

Section C. FACILITIES & EQUIPMENT (The Manufacturing Environmental Controls Prerequisite System)		
No	Question/Notes	Result
C1.1	ESSENTIAL The plant shall demonstrate that the water ice and steam supply is potable and that potability is maintained at all times.	Acceptable
C2.1	The exterior of the Facility is constructed and maintained to facilitate the production of wholesome product and that it at least meets the customer and regulatory food safety and quality requirements.	Acceptable
C2.2	ESSENTIAL Plant construction and layout must be such that exposed product is adequately separated and protected from any operations that could cause contamination.	Acceptable
C3.1	Plant facilities shall be designed and maintained in an orderly, clean condition so as not to impede the ability to thoroughly clean all surfaces, provide pest harborage, or present opportunities for foreign material contamination. <i>There was a small amount of damage near the door of the freezer. There was a wall panel that was uneven and a small gap in the seam. The door to the cooler that was noted in the previous audit had been repaired.</i> <i>NC-The holding freezer had some minor damage near the door on the left side when entering.</i>	Non-conformance*
C4.1	Employee Facilities.	Acceptable
C5.1	Hand wash requirement signs, in appropriate languages and/or graphics, must be clearly posted at required locations and contain instructions as provided below.	Acceptable
C5.2	Hand washing stations shall be adequate, suitably designed, operational and properly stocked	Acceptable
C6.1	ESSENTIAL All food production and packaging equipment must meet food sanitary design requirements and be installed in such a manner as to permit proper operation and access for cleaning and inspection.	Acceptable
C7.1	Utensils & containers used to handle edible material are not used to handle inedible material and are clearly identified and maintained.	Acceptable
C7.2	Air and other gasses used as an aid or part of the process.	Acceptable
C8.1	Plant lighting shall be suitable.	Acceptable
C9.1	Maintenance program and Standards shall be in place.	Acceptable
C9.2	ESSENTIAL Equipment or control devices that impact on food safety are effectively calibrated Equipment or control device that impact on product compliance to quality and regulatory requirements are effectively calibrated Calibration could include, but is not limited to, temperature controllers, flow meters, pressure regulators, divert devices, CIP instrumentation, scales, speed controllers, etc.	Acceptable

Section D. SANITATION, HOUSEKEEPING & HYGIENE		
No	Question/Notes	Result
D1.1	There shall be a Master Sanitation Schedule (MSS) and monitoring and recording of cleaning.	Acceptable
D1.2	There shall be Standard Sanitation Operating Procedures (SSOPs).	Acceptable
D1.3	There shall be a documented Pre-operational Inspection.	Acceptable
D1.4	Operational Housekeeping shall be effective.	Acceptable
D2.1	The facility has a documented program for GMP and Personal Hygiene practices to which compliance is monitored and recorded. <i>All employees were wearing head coverings that covered all hair on the head. The room was less than 40 degrees so many of the workers had stocking caps that completely covered the hair on their head. 3 individuals had short mustaches that were not covered because they were very short.</i> <i>NC-Fine mesh hair restraints were not being worn by all employees.</i>	Non-conformance*
D3.1	GMP Self Inspections shall be completed.	Acceptable

Section E. RODENT & PEST CONTROL MANAGEMENT		
No	Question/Notes	Result
E1.1	There shall be a Documented and Specific Pest Control Program. <i>This was a previous non-conformance and has been corrected.</i>	Acceptable
E1.2	Outside Premises Management shall minimize opportunity for pests <i>The north side of the building has some cracks in the walkway and a fairly large crack between the walkway and the building that could provide pest harborage.</i> <i>NC-Pest harborage is possible on the north side of the building.</i>	Non-conformance*
E1.3	ESSENTIAL There shall be no evidence of infestation.	Acceptable
E1.4	Pest Control Devices shall be properly managed.	Acceptable
E1.5	Doors shall be tight fitting and closed with openings sealed to prevent pest entry into the building <i>This was a previous non-conformance and all doors sealed to prevent pest entry.</i>	Acceptable
E1.6	Pest control reports shall be maintained.	Acceptable

Section F. APPROVED SUPPLIERS, RECEIVING, STORAGE& SHIPPING& INVENTORY CONTROL		
No	Question/Notes	Result
F1.1	There shall be a documented approved supplier program.	Acceptable
F1.2	Suppliers shall be required to provide relevant documentation to support their status as an approved supplier. <i>They raise their own pheasants and purchase packaging for which they have Letters of Conformance.</i>	Acceptable
F2.1	There shall be a written procedure for the inspection of delivery vehicles. This shall apply to receiving and shipping. Procedures shall define when carriers are to be rejected.	Acceptable
F2.2	There shall be a written procedure for the inspection and receipt of ingredients, raw materials, and packaging.	Acceptable
F2.3	There is a written procedure for approval for use of raw materials, ingredients and packaging.	Acceptable
F3.1	Raw materials, ingredients, packaging and finished product shall be secure and protected in storage.	Acceptable
F3.2	Storage temperatures shall be controlled and monitored.	Acceptable
F3.3	Inventory control shall be in place.	Acceptable
F4.1	There shall be policies and practices for the control of Retained and Returned Products.	Acceptable
F4.2	Product can be shipped only with proper authorization.	Acceptable

Section G. PROCESS & PRODUCT EVALUATION		
No	Question/Notes	Result
G1.1	There shall be written specifications and operating procedures to manage compliance to formulation and process parameters.	Acceptable
G1.2	Records of compliance to manufacturing and product specifications shall be available.	Acceptable
G1.3	Rework shall be controlled.	Acceptable
G2.1	There shall be ongoing verification of operational controls and measuring devices.	Acceptable
G3.1	There shall be a documented program to control allergens. <i>There are no allergens used in the facility.</i>	N/A
G3.2	Allergen ingredients shall be controlled. <i>There are no allergens used in the facility.</i>	N/A
G3.3	Controls shall be used to prevent allergen cross-contact. Evidence of cross-contamination with allergens that will result in a threat to health and would result in a Class I or Class II recall shall be assessed as a critical non-conformance. <i>There are no allergens used in the facility.</i>	N/A
G3.4	Personnel must not be a source of cross-contact. <i>There are no allergens used in the facility.</i>	N/A
G3.5	ESSENTIAL Allergen cleaning shall be part of allergen management controls. *Evidence of cross-contamination with allergens that will result in a threat to health and would result in a Class I or Class II recall shall be assessed as a Critical Non-conformance. <i>There are no allergens used in the facility.</i>	N/A
G3.6	ESSENTIAL Documents and products shall be properly labeled with allergen identification and labeling. *Mislabelled product that contain regulated allergens not declared on the label shall be assessed as a critical non-conformance. <i>There are no allergens used in the facility.</i>	N/A

Section H. FOREIGN MATERIAL CONTROL		
No	Question/Notes	Result
H1.1	Open product shall be protected.	Acceptable
H1.2	There shall be a program to manage glass and brittle plastic.	Acceptable
H1.3	Sieves, Filters, and Screens shall be used where appropriate and properly managed and maintained. <i>There are no sieves, filters or screens used for whole bird or whole muscle processing.</i>	N/A
H1.4	Metal detectors shall be managed according to the Metal Detector Operation Expectations, below (see H1.4.1). Metal detection systems shall include the detection head and a reject device. Similar procedures shall be employed for X-ray detectors. <i>They only package whole birds or whole muscle product that are hand cut with a stringent blades policy with all blades continually accounted for and inspected.</i>	N/A
H1.4.1	Metal detectors shall be managed according to the Metal Detector Operation Expectations. <i>There are no allergens used in the facility.</i>	N/A
H1.5	Blades where used shall be controlled and inspected.	Acceptable

Section I. CHEMICAL CONTROL		
No	Question/Notes	Result
I1.1	Non-food chemicals shall be approved for use, securely stored, clearly identified and used by trained persons	Acceptable
I1.2	Lubricants shall be properly stored and identified. <i>Very limited number of lubricants as there is no mechanical processing equipment.</i>	Acceptable
I1.3	Pest Control Chemicals shall be properly stored.	Acceptable
I1.4	Cleaning Chemicals and Sanitizer shall be securely stored.	Acceptable

Section J. PACKAGING & LABELING		
No	Question/Notes	Result
J1.1	ESSENTIAL Labels shall be accurate and comply with all regulations.	Acceptable
J1.2	ESSENTIAL The product shall comply with regulation or specifications for net weight, net quantity or piece count. <i>This was a previous non-conformance that has been addressed. They have a scale and computer that is used to weigh and a SOP explaining how this is done.</i>	Acceptable
J1.3	Clearly visible and legible Codes on Individual and Cased Product.	Acceptable
J1.4	The packaging Integrity and Function shall adequately protect the product.	Acceptable

Section K. TRAINING REQUIREMENTS		
No	Question/Notes	Result
K1.1	New employee and temp employees shall be trained in appropriate policies and procedures.	Acceptable
K1.2	Training shall be conducted in the appropriate language(s). <i>Much of the training is one on one with only 8 employees and multiple management level persons included in the 8. Management is on the floor working daily.</i>	Acceptable
K1.3	Refresher Training shall be conducted.	Acceptable
K1.4	There shall be a method of to determine Proof of Knowledge following training.	Acceptable
K1.5	Training Records shall be maintained. <i>Signed GMP statements.</i>	Acceptable

Section L. LABORATORY SUPPORT		
No	Question/Notes	Result
L1.1	The laboratory facility and staffing shall not contribute to potential contamination. <i>There is no laboratory.</i>	N/A
L1.2	Laboratory Procedures and Documentation shall meet recognized standards. <i>There is no laboratory.</i>	N/A
L1.3	Laboratory Equipment shall be calibrated. <i>There is no laboratory.</i>	N/A

Section M. FOOD DEFENSE		
No	Question/Notes	Result
M1.1	A Food Defense team Shall be established that will evaluate the vulnerabilities and risks that exist from ingredient sourcing, storage, processing, shipping of finished goods, and personnel.	Acceptable
M1.2	Each facility must conduct and document a Food Defense Risk Evaluation to eliminate or significantly reduce the risk of external and internal intentional adulteration of food. Note: No details of food defense control measures will be identified in the audit report unless requested by the plant.	Acceptable
M1.3	A comprehensive food defense plan shall be implemented to manage the risks identified in the evaluation that shall include: a. Security assessment of off -site storage; b. Protection of air, gas and water supplies; c. Protection of process control systems; d. Protection of environmental control systems; e. Protection of sensitive data systems and the data (formulations, specifications, business information, etc.); f. Identification and management of unusual occurrences.	Acceptable
M1.4	Employees shall be screened, trained in Food defense awareness and reporting and access to the facility shall be controlled.	Acceptable
M1.5	Incoming and outgoing materials shall be protected and inspected.	Acceptable
M1.6	Plants shall be registered with the appropriate regulatory authority. In the USA or if exporting to the U.S.A. then the plant, warehouse or distribution center must demonstrate proof of having registered their facility with the FDA under the PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002 or the USDA, as applicable. <i>They are a Federally inspected meat plant and are registered accordingly.</i>	Acceptable

Section N. READY TO EAT (RTE) FOODS PROCESSING REQUIREMENTS		
No	Question/Notes	Result
N1.1	Airborne contaminants shall be minimized. <i>All products are raw and must be cooked.</i>	N/A
N1.2	Protective Clothing shall be used to minimize potential of cross-contact. <i>All products are raw and must be cooked.</i>	N/A
N1.3	RTE Entrance Sanitation Controls. <i>All products are raw and must be cooked.</i>	N/A
N1.4	Environmental Pathogen Monitoring shall be implemented. <i>All products are raw and must be cooked.</i>	N/A

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