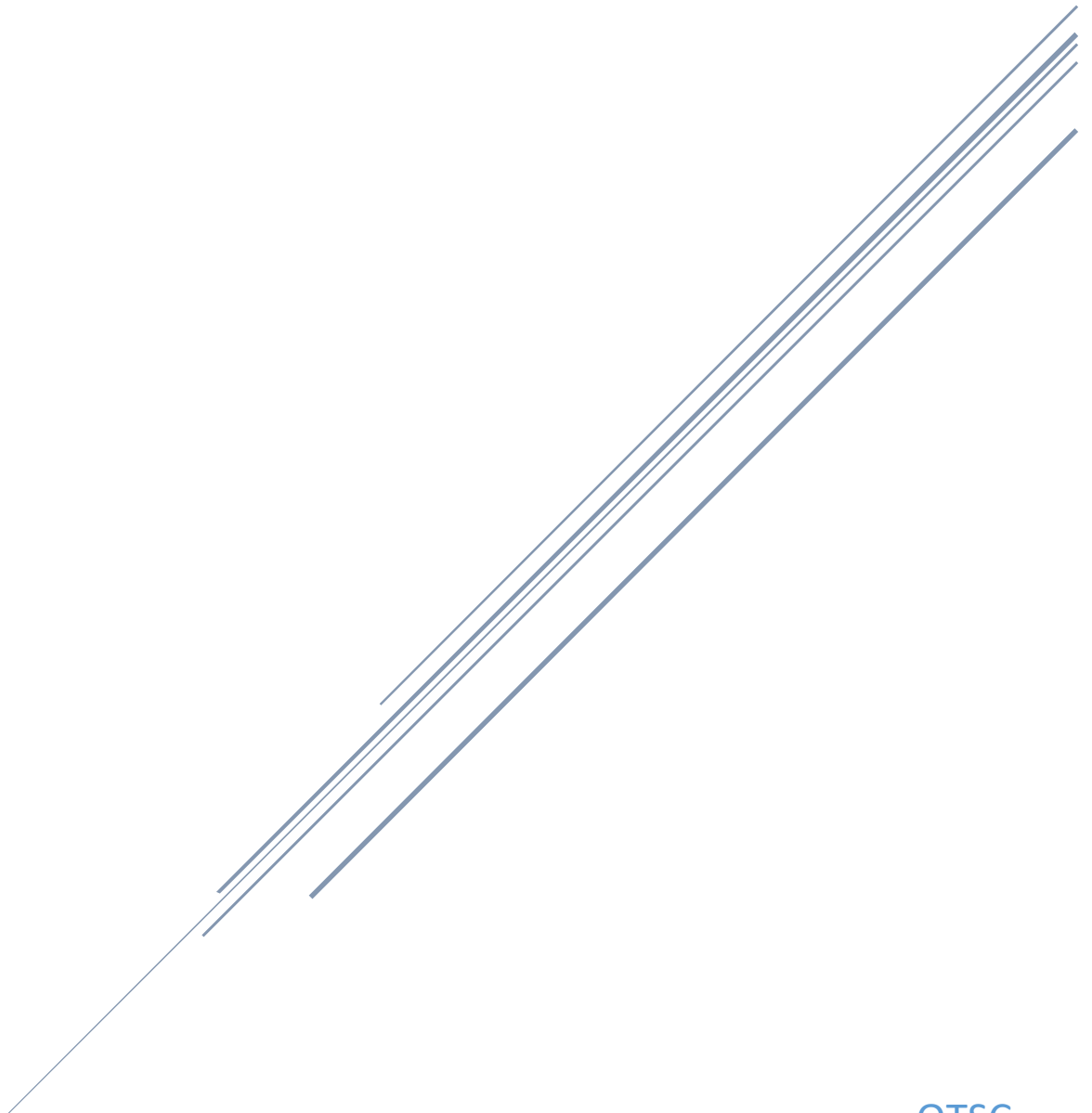


MODEL FOOD SAFETY PLAN FOR A RAW DOG/CAT FOOD WITHOUT HEAT PROCESSING

FSMA Activity - 2021

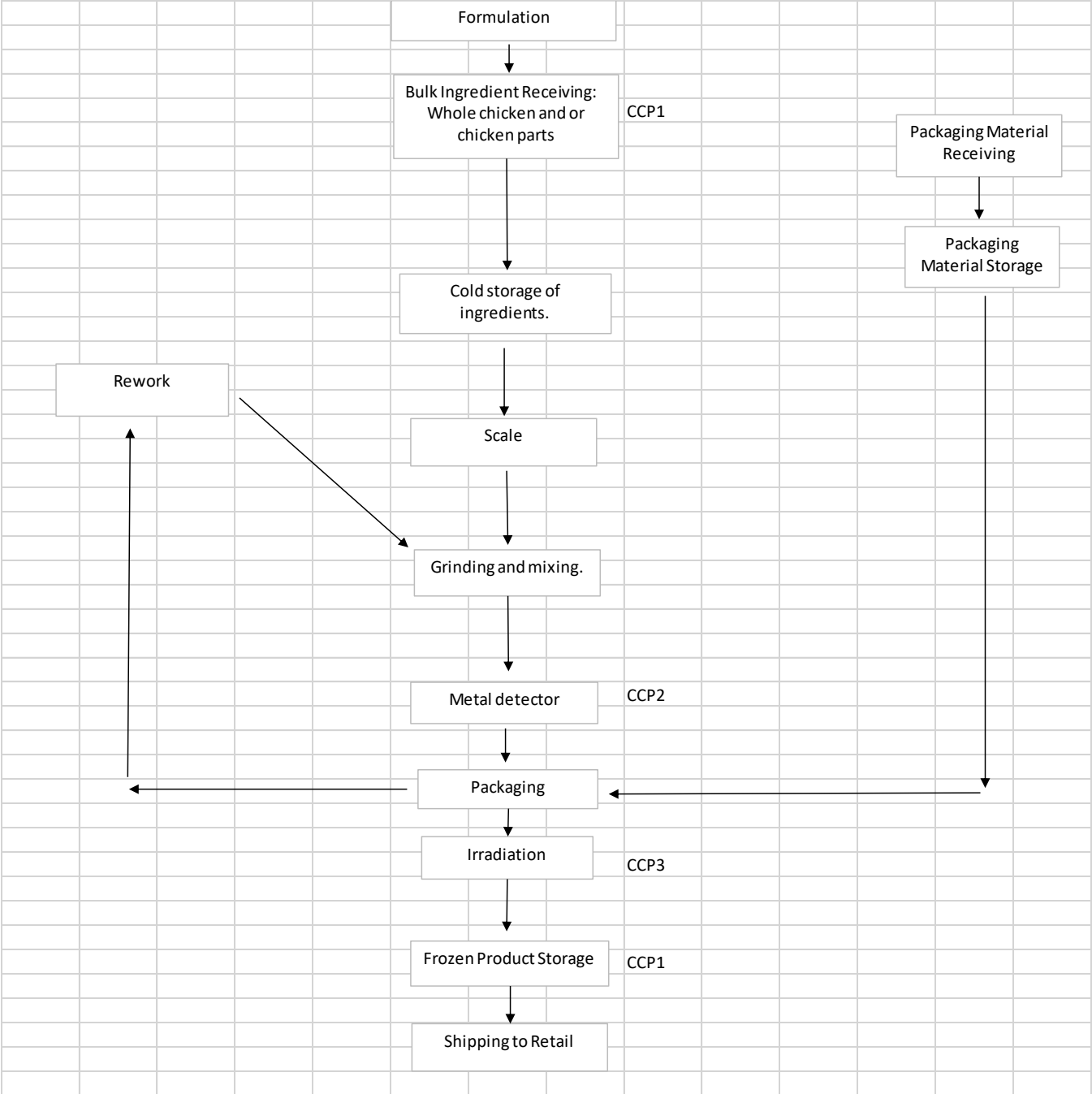


OTSC
FSMA Activity

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Owner or Agent in Charge Signature



List of Product Ingredients and Incoming Materials Form (1)

Product Category: Manufacturer of Dog and Cat Food that has Not Undergone a Heat Process

Specific product category: Raw frozen dog and cat food. Complete or for intermittent feeding.

Bulk Ingredients	Bag, and Hand Add Ingredients	Medications/Drugs
Whole chicken with bone	None	None
Liquids	Packaging Materials	Other Additives
Water (if batch is dry)	Plastic chub suitable for irradiation Outer cardboard box for shipping chubs. Lined with plastic.	None

Approved PCQI: DKR

Date: 8/2/2021

Product Description Form (2)

Product Category: Raw frozen dog and cat food. Complete and or for intermittent feeding (treat)

1. Product name(s)	Ground Chicken with Bone
2. Product safety properties (Moisture, Temperature, NPN, etc.)	Frozen product with high moisture. Animal protein product.
3. Intended use and customer	Dog and cat food.
4. Type of packaging	Sealed plastic chub that is suitable for HPP or irradiation. Shipped in plastic lined cardboard boxes.
5. Shelf life	6 months to 12 months
6. Where will the product be sold?	Pet food stores, feed stores, general retail establishments.
7. Labeling instructions	Keep product frozen until ready to use. Thaw in refrigerator before feeding. Discard uneaten portions. This product is meant for intermittent or supplemental feeding only. Not a complete feed. Always wash hands and utensils after handling. Treated with irradiation.
8. Special distribution control	Must be transported in refrigerator trucks kept at freezing temperatures.

Approved: DKR

Date: 8/2/2021

Hazard Analysis Form (4)

Product Category: Animal Food #3 –Non heat processed dog/cat food

Intended Species: Dog/Cat

Life Stage: All life stages.

Ingredient or Process Step	Known or reasonably foreseeable hazards introduced, increased or controlled at this step	Do known or reasonably foreseeable hazards require a preventive control based on Severity and Probability “Yes” or “No”	Explanation/Justification	Preventive Control Measures Applied	Is the Preventive Control Applied at this Step? “Yes” or “No”
1. Formulation	Biological Listeria Salmonella	Yes	Raw poultry is a known source of Salmonella. Controlling temperature with help keep growth (if present) in check.	Process control: Temperature	Yes, CCP1
	Chemical None identified at this time.				
	Physical None identified at this time				

Date: 7/19/2021 PCQI Initial: DKR

Hazard Analysis Form (4)

Product Category: Animal Food Non heat processed dog/cat food

Intended Species: Dog/Cat

Life Stage: All life stages.

Ingredient or Process Step	Known or reasonably foreseeable hazards introduced, increased or controlled at this step	Do known or reasonably foreseeable hazards require a preventive control based on Severity and Probability "Yes" or "No"	Explanation/Justification	Preventive Control Measures Applied	Is the Preventive Control Applied at this Step? "Yes" or "No"
2. Receiving whole chicken/chicken parts (frozen)	Biological Listeria, Salmonella	Yes	Raw poultry is a known source of pathogens. Controlling temperature with help keep growth (if present) in check.	Process control: Temperature	Yes, CCP1
	Chemical Cleaners, sanitizers, pesticides Animal drug residue	No	Low likelihood: approved supplier including letter of guarantee, SSOPs.		
	Physical Plastic, metal, wood,	No	Low likelihood. Metal controlled at metal detector.		

Date: 7/19/2021 PCQI Initial: DKR

Hazard Analysis Form (4)

Product Category: Animal Food #3 –Non heat processed dog/cat food

Intended Species: Dog/Cat

Life Stage: All life stages.

Ingredient or Process Step	Known or reasonably foreseeable hazards introduced, increased or controlled at this step	Do known or reasonably foreseeable hazards require a preventive control based on Severity and Probability "Yes" or "No"	Explanation/Justification	Preventive Control Measures Applied	Is the Preventive Control Applied at this Step? "Yes" or "No"
3. Packaging Material Receiving 4. Packaging Material Storage	Biological 3. None identified at this time 4. Listeria Salmonella	No	4. GMPs and SOPs will prevent contamination of packaging materials.		
	Chemical 3. Cleaners/residues from manufacture 4. Cleaners, sanitizers, pesticides.	No	3. Letters of guarantee from suppliers. Packaging must be designed and approved for irradiation/direct contact with food. 4. CGMPs.		
	Physical 3. None identified at this time 4. Fragments of plastic, metal, wood.	No	4. Letters of guarantee from approved suppliers.		

Date: 7/19/2021 PCQI Initial: DKR

Hazard Analysis Form (4)

Product Category: Animal Food #3 –Non heat processed dog/cat food

Intended Species: Dog/Cat

Life Stage: All life stages.

Ingredient or Process Step	Known or reasonably foreseeable hazards introduced, increased or controlled at this step	Do known or reasonably foreseeable hazards require a preventive control based on Severity and Probability "Yes" or "No"	Explanation/Justification	Preventive Control Measures Applied	Is the Preventive Control Applied at this Step? "Yes" or "No"
5. Cold storage of ingredients (frozen)	Biological Listeria Salmonella	No	No significant growth of pathogens will occur at low temperatures of cold storage.		
	Chemical Cleaners, sanitizers, Pesticides	No	Low likelihood resulting from SSOPs.		
	Physical None identified at this time.				

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Hazard Analysis Form (4)

Product Category: Animal Food #3 –Non heat processed dog/cat food

Intended Species: Dog/Cat

Life Stage: All life stages.

Ingredient or Process Step	Known or reasonably foreseeable hazards introduced, increased or controlled at this step	Do known or reasonably foreseeable hazards require a preventive control based on Severity and Probability "Yes" or "No"	Explanation/Justification	Preventive Control Measures Applied	Is the Preventive Control Applied at this Step? "Yes" or "No"
5. Scale	Biological Listeria Salmonella	No	Low likelihood resulting SSOPs.		
	Chemical: None identified at this time				
	None identified at this time				

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Hazard Analysis Form (4)

Product Category: Animal Food #3 –Non heat processed dog/cat food

Intended Species: Dog/Cat

Life Stage: All life stages.

Ingredient or Process Step	Known or reasonably foreseeable hazards introduced, increased or controlled at this step	Do known or reasonably foreseeable hazards require a preventive control based on Severity and Probability "Yes" or "No"	Explanation/Justification	Preventive Control Measures Applied	Is the Preventive Control Applied at this Step? "Yes" or "No"
6. Tempering (warming meat to just below its freezing point)	Biological Listeria Salmonella	No	Product will only be allowed warmed to a temperature right below freezing point to allow for easier grinding. If any bacteria present it will be killed in future step.		
	Chemical Sanitizers, cleaners	No	Low likelihood resulting from implementing SSOPs.		
	Physical None identified at this time				

Date: 7/19/2021 PCQI Initial: DKR

Hazard Analysis Form (4)

Product Category: Animal Food #3 –Non heat processed dog/cat food

Intended Species: Dog/Cat

Life Stage: All life stages.

Ingredient or Process Step	Known or reasonably foreseeable hazards introduced, increased or controlled at this step	Do known or reasonably foreseeable hazards require a preventive control based on Severity and Probability "Yes" or "No"	Explanation/Justification	Preventive Control Measures Applied	Is the Preventive Control Applied at this Step? "Yes" or "No"
7. Grinding/Mixing	Biological Listeria Salmonella	No	Low likelihood resulting from SSOPs.		
	Chemical Disinfectants, cleaners,	No	Low likelihood resulting from SSOPs and GMP procedures.		
	Physical Plastic, metal, wood, .	No	Low likelihood. Visual inspection while mixing and metal detector at later step.		

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Hazard Analysis Form (4)

Product Category: Animal Food #3 –Non heat processed dog/cat food

Intended Species: Dog/Cat

Life Stage: All life stages.

Ingredient or Process Step	Known or reasonably foreseeable hazards introduced, increased or controlled at this step	Do known or reasonably foreseeable hazards require a preventive control based on Severity and Probability "Yes" or "No"	Explanation/Justification	Preventive Control Measures Applied	Is the Preventive Control Applied at this Step? "Yes" or "No"
8. Product moved through metal detector.	Biological Listeria Salmonella	No	Low likelihood of bacteria resulting from SSOPs.		
	Chemical Cleaners/sanitizers	No	Low likelihood resulting from SSOPs that will prevent cleaner residues from entering product and GMPS.		
	Physical Plastic, metal, wood.	Yes	Harmful to customer if metal contaminates product.	Process control: metal detector.	Yes, CCP 2

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Hazard Analysis Form (4)

Product Category: Animal Food #3 –Non heat processed dog/cat food

Intended Species: Dog/Cat

Life Stage: All life stages.

Ingredient or Process Step	Known or reasonably foreseeable hazards introduced, increased or controlled at this step	Do known or reasonably foreseeable hazards require a preventive control based on Severity and Probability "Yes" or "No"	Explanation/Justification	Preventive Control Measures Applied	Is the Preventive Control Applied at this Step? "Yes" or "No"
9. Packaging	Biological Listeria Salmonella	No	Sanitation SOPs will address the potential contamination of product during packaging.		
	Chemical cleaners, pesticides.	No	Low likelihood resulting from SSOPs that will prevent cleaner residues from entering product and GMPS.		
	Physical Plastic,	No	Low likelihood resulting from visual inspection of product while packaging (SOP).		

Date: 7/19/2021 PCQI Initial: DKR

Hazard Analysis Form (4)

Product Category: Animal Food #3 –Non heat processed dog/cat food

Intended Species: Dog/Cat

Ingredient or Process Step	Known or reasonably foreseeable hazards introduced, increased or controlled at this step	Do known or reasonably foreseeable hazards require a preventive control based on Severity and Probability "Yes" or "No"	Explanation/Justification	Preventive Control Measures Applied	Is the Preventive Control Applied at this Step? "Yes" or "No"
10. Individually quick freezing packaged product. (to get product to final storage temperature)	Biological Listeria Salmonella	No	Low likelihood resulting temperature control		
	Chemical Cleaners sanitizers	No	Low likelihood resulting from SSOPs and GMP procedures.		
	Physical None identified at this time				

Life Stage: All life stages.

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Hazard Analysis Form (4)

Product Category: Animal Food #3 –Non heat processed dog/cat food

Intended Species: Dog/Cat

Ingredient or Process Step	Known or reasonably foreseeable hazards introduced, increased or controlled at this step	Do known or reasonably foreseeable hazards require a preventive control based on Severity and Probability "Yes" or "No"	Explanation/Justification	Preventive Control Measures Applied	Is the Preventive Control Applied at this Step? "Yes" or "No"
11. Irradiation	Biological Pathogenic bacteria	Yes	Control step to eliminate pathogenic bacteria like Salmonella, Listeria, and E. coli O157:H7.	Process control using Irradiation of product at allowed dose range per CFR for poultry products.	Yes. CCP 3
	Chemical Disinfectants, cleaners, pesticides.	No	Low likelihood resulting from SSOPs and GMP procedures		
	Physical None identified at this time				

Life Stage: All life stages.

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Hazard Analysis Form (4)

Product Category: Animal Food #3 –Non heat processed dog/cat food

Intended Species: Dog/Cat

Life Stage: All life stages.

Ingredient or Process Step	Known or reasonably foreseeable hazards introduced, increased or controlled at this step	Do known or reasonably foreseeable hazards require a preventive control based on Severity and Probability "Yes" or "No"	Explanation/Justification	Preventive Control Measures Applied	Is the Preventive Control Applied at this Step? "Yes" or "No"
12. Frozen Product Storage	Biological Pathogenic bacteria	Yes	Correct temperature storage after irradiation will prevent growth of bacteria and maintain product freshness.	Process control using Temperature	Yes. CCP1
	Chemical Disinfectants, cleaners, insecticides	No	Low likelihood resulting from SSOPs and GMP procedures		
	Physical None identified at this time				

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Hazard Analysis Form (4)

Product Category: Animal Food #3 –Non heat processed dog/cat food

Intended Species: Dog/Cat

Life Stage: All life stages.

Ingredient or Process Step	Known or reasonably foreseeable hazards introduced, increased or controlled at this step	Do known or reasonably foreseeable hazards require a preventive control based on Severity and Probability "Yes" or "No"	Explanation/Justification	Preventive Control Measures Applied	Is the Preventive Control Applied at this Step? "Yes" or "No"
13. Shipping to retail	Biological		Correct temperature storage after irradiation will prevent growth of bacteria and maintain product freshness.	Process control using Temperature	Yes. CCP1
	Chemical Disinfectants, cleaners, pesticides	No	Low likelihood resulting from SSOPs and GMP procedures		
	Physical Wood Metal Plastic	No	Low likelihood resulting from visual inspection of carrier SOP.		

Date: 7/19/2021 PCQI Initial: DKR

Identifying Critical Limits, Monitoring and Corrective Actions Form (5)

Process Step/CCP	Critical Limit	Monitoring Procedures	Corrective Action
<p>CCP1 Controlling temperature at receiving. Controlling temperature in ingredient freezer and finished product freezer.</p>	<p>Receiving: Product should be at or below 10° F (-12°C)</p> <p>Storage: Ingredients and finished product should be stored at 0°F or -17°C.</p>	<p>What will be measured? Temperature of incoming ingredients and the temperature of storage freezers.</p> <p>Where will the CL be measured? At receiving and during storage.</p> <p>How will the CL be measured? Surface temperature of incoming ingredients will be taken with an infrared thermometer. In storage freezers the temperature will be monitored with a commercial grade system with alarm.</p> <p>Who will monitor the CL? By a trained and responsible plant employee.</p> <p>How often will the CL be measured? Freezer will be monitored 24 hours a day. Each batch of incoming ingredients will be checked.</p>	<p>Cause of the deviation? Hold product, evaluate why deviation is occurring. If incoming ingredient temperature is too high reject load.</p> <p>How will the process be corrected? Make sure supplier follows correct temperature for shipping. Also, depends on issue. Review process and determine causes.</p> <p>Product disposition? Reject product if above Reject product if product not frozen when received. Dispose of product if freezers fail (unlikely with monitoring system)</p> <p>Measure to prevent recurrence? Instructions to supplier what temperature the product should be shipped at. Proper inspection and maintenance of freezers.</p> <p>Who is responsible for implementing the CA? A trained and responsible plant employee. PC can review decisions made.</p>

Approved: DKR

Date: 8/2/2021

Identifying Critical Limits, Monitoring and Corrective Actions Form (5)

Process Step/CCP	Critical Limit	Monitoring Procedures	Corrective Action
<p>CCP2: Metal detector</p>	<p>Any detection of metal in product.</p> <p>All product will pass through metal detector.</p>	<p>What will be measured? Metal fragments (if any) found in ground product.</p> <p>Where will the CL be measured? On the production line right after grinding and mixing.</p> <p>How will the CL be measured? With a commercial grade metal detector designed for meat processing facility.</p> <p>Who will monitor the CL? A trained and responsible employee will monitor the metal detector.</p> <p>How often will the CL be measured? During production. Continuous.</p>	<p>Cause of the deviation?</p> <p>A cause of deviation would be metal fragments found in ground product.</p> <p>How will the process be corrected?</p> <p>Hold. Stop production and check equipment for broken or loose parts. Review maintenance records and process procedures. Check metal detector and repair if needed.</p> <p>Product disposition?</p> <p>Dispose of any product if metal detected in that batch.</p> <p>Measure to prevent recurrence?</p> <p>Check metal detector at start of day, middle of shift, and end of day with controls.</p> <p>Who is responsible for implementing the CA?</p> <p>A trained and responsible employee.</p>

Approved: DKR

Date: 8/2/2021

Identifying Critical Limits, Monitoring and Corrective Actions Form (5)

Process Step/CCP	Critical Limit	Monitoring Procedures	Corrective Action
<p>CCP3: Irradiation of packaged product</p>	<p>D_{min} and D_{max} according to FDA, USDA/FSIS approved protocols. Which includes the time of process and dose mapping for ground poultry products. (1.5 to 3.0 kGy)</p>	<p>What will be measured? Dosimetry to measure actual absorbed dose and dose mapping. Microbial testing.</p> <p>Where will the CL be measured? In production facility after irradiation.</p> <p>How will the CL be measured? Dosimetry shows correct amount of ionizing radiation absorbed. Lack of pathogenic bacteria found in sampled products.</p> <p>Who will monitor the CL? A trained and responsible employee.</p> <p>How often will the CL be measured? Monthly or more frequent by volume and other factors. Microbial testing can be done by outside lab as well to verify process.</p>	<p>Cause of the deviation? If exceeding D_{max} dispose of product. If not reaching D_{min} then evaluate process and adjust to reach correct levels. Dispose of product as well.</p> <p>How will the process be corrected? By reviewing the process and determining what caused the issue.</p> <p>Product disposition? See above comments. If microbial contamination found dispose of that batch produced.</p> <p>Measure to prevent recurrence? Daily follow SSOPs and review relevant HACCP records. Proper training of employees as well.</p> <p>Who is responsible for implementing the CA? A trained and responsible employee.</p>

Approved: DKR

Date: 8/2/2021

Record Keeping and Verification Form (6)

Process step/CCP	Hazard	Records	Responsibility	CCP Verification
CCP1: Incoming ingredient temperature and storage freezer temperature	Growth of pathogenic bacteria <i>Listeria monocytogenes</i> , <i>Salmonella</i> ,	Receiving log recorded at CCP site on a real time basis. Thermometer calibration log. Hold log. Deviation and corrective action log. All logs will be completed by a designated employee.	Designated employees who report to PC.	Short term Calibrate thermometers and monitoring system for storage freezers. Review records daily or weekly depending on production amounts. Long term Perform ongoing review of HACCP plan in response to deviations and or system and product modification.

Approved: DKR

Date: 8/2/2021

Record Keeping and Verification Form (6)

Process step/CCP	Hazard	Records	Responsibility	CCP Verification
<p>CCP2: Metal detector after grinding and mixing.</p>	<p>Metal fragments found in ground product.</p>	<p>Calibration log of metal detector.</p> <p>Sensitivity check log of metal detector.</p> <p>Hold log.</p> <p>Deviation and correct action log.</p> <p>All logs will be completed by a designated employee.</p>	<p>A trained and designated person who reports to PC.</p>	<p>Short term</p> <p>Daily testing of metal detector as needed and calibration once a month.</p> <p>Long term</p> <p>Perform ongoing review of HACCP plan in response to deviations and or system and product modifications.</p>

Approved: DKR

Date: 8/2/2021

Record Keeping and Verification Form (6)

Process step/CCP	Hazard	Records	Responsibility	CCP Verification
<p>CCP3: Irradiation of packaged product.</p>	<p>Control of pathogenic bacteria like <i>Listeria monocytogenes</i>, <i>Salmonella</i>,</p>	<p>Records of poultry processing required by 9 CFR 381.145.</p> <p>Preventative maintenance records.</p> <p>Inoculated pack study records.</p> <p>Deviation and corrective action log completed by designated employee.</p>	<p>A trained and designated person who reports to PC.</p>	<p>Short term</p> <p>Dosimetry calibration, Inoculated Pack studies and microbial testing as deemed necessary based on volume produced.</p> <p>Long term</p> <p>Perform ongoing review of Food Safety plan in response to deviations and or system and product modifications.</p>

Approved: DKR

Date: 8/2/2021

Animal Food Safety Plan Summary Form (8)

Process step and CCP	Hazard	Critical Limits for each CCP	Monitoring				Corrective Action	Verification Activities	Record-keeping Procedure
			What	How	Frequency	Who			
CCP1: Controlling temperature at receiving. Controlling temperature in both the ingredient freezer and finished product freezer.	Pathogenic bacteria growth. Examples: like <i>Listeria monocytogenes</i> , <i>Salmonella</i> ,	Receiving: Product should be at or below 10° F (-12°C) Storage: Ingredients and finished product should be stored at 0°F or -17°C.	Temperature of incoming ingredients. Temperature of freezers.	Incoming ingredient temperature with infrared thermometer Freezer temperature with commercial grade thermometer system with alarm/recording system.	Each incoming batch. Freezer temperature 24 hours a day.	Both measured by trained and responsible plant employee.	Hold product, evaluate why deviation is occurring. Reject product if need be. Review process and update if problems keep occurring.	Calibrate thermometers and monitoring system for freezers. Review records daily or weekly depending on production amounts.	Receiving log at CCP site on a real time basis. Thermometer calibration log. Hold log. Deviation and corrective action log. All logs will be completed by a designated employee.
CCP 2: Metal detector	Fragments of ground metal in product.	Any detection of metal in product.	Metal fragments if any found in ground product.	With commercial grade metal detector designed for a meat processing facility.	Continuous. During production.	A trained and responsible plant employee.	Hold product, stop production and check equipment for broken or loose parts. Review maintenance records and process procedures. Check metal detector and repair if needed. Dispose of product batch if need be.	Daily testing of metal detector (sensitivity controls). And calibration once a month.	Calibration log of metal detector. Sensitivity check log of metal detector. Hold log. Deviation and corrective action log. All logs will be completed by a designated employee.

CCP3: Irradiation of packaged product	Control of pathogenic bacteria like <i>Listeria monocytogenes</i> , <i>Salmonella</i> ,	D _{min} and D _{max} according to FDA, USDA/FSIS approved protocols. Which includes the time of process and dose mapping for ground poultry products. (1.5 to 3.0 kGy)	Dosimetry to measure actual absorbed dose and dose mapping. Microbial testing.	Dosimetry shows correct amount of ionizing radiation absorbed. Lack of pathogenic bacteria found in sampled products.	Monthly or more frequent by volume and other factors. Microbial testing can be done by outside lab as well to verify process.	A trained and responsible employee.	If exceeding D _{max} dispose of product. If not reaching D _{min} then evaluate process and adjust to reach correct levels. Dispose of product as well.	Dosimetry calibration, Inoculated Pack studies and microbial testing as deemed necessary based on volume produced. Perform ongoing review of HACCP plan in response to deviations and or system/product modifications.	Records of poultry processing required by 9 CFR 381.145. Preventative maintenance records. Inoculated pack study records. Deviation and corrective action log completed by designated employee.
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Approved DKR

Date: 8/2/2021

