

2.4.3B - PRODUCT DESCRIPTION & INTENDED USE

Scope of Hazard Analysis:	Receiving of pre-washed & cored cabbage and pre-washed and cut non-cabbage vegetables and seasoning. Materials held at 36°F. Products fermented for 30 days under controlled conditions, packaged, labeled and sealed in hard plastic & film plastic containers. Stored on site & at off site warehouse and distribution
Purpose of HACCP Analysis:	Identify potential hazards associated with raw vegetables and processing of raw vegetables as they pertain to Food Safety and Quality
Product Description: A brief description of the product and how it is presented	Fermented cabbage & seasonings (sauerkraut) with other vegetables.
Composition: Statement of ingredients where appropriate	Red Beets, Carrots, Jalapenos, Garlic, Dill Weed, Ginger, Green Bell Peppers, Leeks, Cucumbers, Black Pepper, Turmeric, Cumin, Coriander, Yellow Mustard Seed, Caraway Seed, Red Chili Flakes, Cleveland Whiskey, Kosher Salt, Sriracha Chili Sauce.
Method of Preservation: What methods are used in ensure product meets its shelf life?	Fermentation, Acidity ≤ 4.6 , Packaging.
Packaging Primary: Unit of sale/packaging - size, grade of material	Heat sealed Poly Bag without modified atmosphere. Food Service Plastic Pails
Packaging - Shipping/secondary: Packaging that product is transported in or upon-shipping carton and pallet.	Outer master corrugated case. Wooden and or Plastic pallet
Storage Conditions: Conditions under which the finished product is to be held prior to dispatch and held by customer prior to use - temperature, RH	Product is stored in temperature controlled and recorded storage facilities <35-40 °F
Distribution Method: Conditions under which the finished product is to be transported to the customer - chilled, frozen - include temperature range	Product is distributed in temperature documented refrigerated trucks <35-40 °F
Shelf Life: Minimum time period before product exhibits noticeable quality changes or microbial levels become unsafe when stored under specified storage conditions: May also include shelf life after opening if appropriate.	Retail: 365 Days after manufacture
	Food Service: 180 Days after Manufacture

Cleveland Kraut is a Proprietary Trade Secret and Confidential Commercial Information. Exempt from disclosure of the under the Freedom of Information Act, 5 U.S.C. 552(b)(4)

Special Labeling: Additional labelling, other than required by the FSC, to describe the product, grower code, storage conditions, warnings, preparation advice	Keep product refrigerated
Intended Customer:	General Public
Customer Preparation: How the product is intended to be prepared by the consumer prior to consumption?	Product is ready to eat.
Sensitive Population: Is the product specifically marketed at a sensitive population such as infants or elderly?	May not be suitable for children under the age of 1
Does the product contain ingredients that may be hazardous to sensitive members of the community at large - e.g. peanuts, gluten)	Product does not contain Allergens or Gluten containing materials

APPROVED			
Signature on file?	NAME	TITLE	DATE
x	Don Asplin	Consultant	10/17/17

CHANGE CONTROL			
CHANGE	REASON	NAME	DATE
	New Policy	Don Asplin	10/17/17
Packaging Change	Packaging change	Luke Visnic	9/20/18
Graphic updates	Legibility	Luke Visnic	10/11/18

2.4.3D - FOOD SAFETY RISK ANALYSIS MATRIX

		FREQUENCY				
		A COMMON	B KNOWN TO OCCUR	C COULD OCCUR	D NOT EXPECTED	E PRACTICALLY IMPOSSIBLE
SEVERITY	1 FATAL	HIGH	HIGH	HIGH	HIGH	MEDIUM
	2 SERIOUS ILLNESS	HIGH	HIGH	HIGH	MEDIUM	MEDIUM
	3 PRODUCT RECALL	HIGH	HIGH	HIGH	MEDIUM	LOW
	4 CUSTOMER COMPLAINT	MEDIUM	MEDIUM	MEDIUM	LOW	LOW
	5 INSIGNIFICANT	LOW	LOW	LOW	LOW	LOW

APPROVED			
Signature on File?	NAME	TITLE	DATE
X	Don Asplin	Consultant	10/27/17

CHANGE CONTROL			
CHANGE	REASON	NAME	DATE
	New Policy	Don Asplin	10/27/17
Graphic change	Legibility	Luke Visnic	9/20/18

2.4.3E - INGREDIENT RISK ANALYSIS

LEGEND

B - Biological Hazards include bacteria, viruses & environmental pathogens.

C - Chemical Hazards include food allergens, substances such as pesticides & drug residue, natural toxins, radiological, decompositions & unapproved food colors and/or additives.

P - Physical Hazards include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
Green & Red Cabbage	B	Micro sensitive ingredient (Salmonella, Listeria)	Product is harvested directly from the field	3	B	HIGH	Yes Supplier Approval	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Pesticides and Herbicides	Farm practices not implemented	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Soy, Wheat Cross Contact	Potential cross contact with other allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
Red Beets	B	Micro sensitive ingredient (Salmonella, Listeria)	Product is harvested directly from the field	3	B	HIGH	Yes Supplier Approval	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Pesticides and Herbicides Residues	Farm practices not implemented	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Soy, Wheat Cross Contact	Potential cross contact with other allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
Carrots	B	Micro sensitive ingredient (Salmonella, Listeria)	Product is harvested directly from the field	3	B	HIGH	Yes Supplier Approval	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Pesticides and Herbicides	Farm practices not implemented	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Soy, Wheat Cross Contact	Potential cross contact with other allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
Green Jalapenos	B	Micro sensitive ingredient (Salmonella, Listeria)	Product is harvested directly from the field	3	B	HIGH	Yes Supplier Approval	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Pesticides and Herbicides Residues	Farm practices not implemented	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Soy, Wheat Cross Contact	Potential cross contact with other allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
Minced Garlic	B	Micro sensitive ingredient (Campylobactor jejuni)	Product is harvested directly from the field	3	B	HIGH	Yes Supplier Approval	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Pesticides and Herbicides	Farm practices not implemented	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Soy, Wheat Cross Contact	Potential cross contact with other allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
Dill Weed	B	Micro sensitive ingredient (Salmonella)	Product is harvested directly from the field	3	B	HIGH	Yes Supplier Approval	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Pesticides and Herbicides Residues	Farm practices not implemented	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Soy, Wheat Cross Contact	Potential cross contact with other allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
Grated Ginger	B	Micro sensitive ingredient (Bacillus cereus, Clostridium botulinum, C. perfringens, E.coli, Salmonella)	Product is harvested directly from the field	3	B	HIGH	Yes Supplier Approval	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Pesticides and Herbicides	Farm practices not implemented	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Mycotoxingenic jungi	Associated with spices and some vegetable	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Allergen Cross Contact	Potential cross contact with allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
Green Bell Peppers	B	Micro sensitive ingredient (Salmonella, Listeria)	Product is harvested directly from the field	3	B	HIGH	Yes Supplier Approval	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Pesticides and Herbicides Residues	Farm practices not implemented	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Soy, Wheat Cross Contact	Potential cross contact with other allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
Leeks	B	Micro sensitive ingredient (Campylobactor jejuni)	Product is harvested directly from the field	3	B	HIGH	Yes Supplier Approval	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Pesticides and Herbicides	Farm practices not implemented	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Soy, Wheat Cross Contact	Potential cross contact with other allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
Cucumbers	B	Micro sensitive ingredient (Salmonella, Listeria)	Product is harvested directly from the field	3	B	HIGH	Yes Supplier Approval	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Pesticides and Herbicides Residues	Farm practices not implemented	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Soy, Wheat Cross Contact	Potential cross contact with other allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
Black Pepper	B	Micro sensitive ingredient (Campylobacter jejuni)	Product is harvested directly from the field	3	B	HIGH	Yes Supplier Approval	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Pesticides and Herbicides	Farm practices not implemented	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Mycotoxingenic fungi	Associated with spices and some vegetable	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Allergen Cross Contact	Potential cross contact with allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
Turmeric	B	Micro sensitive ingredient (Bacillus cereus, Clostridium botulinum, C. perfringens, E.coli, Salmonella)	Product is harvested directly from the field	3	B	HIGH	Yes Supplier Approval	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Pesticides and Herbicides Residues	Farm practices not implemented	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Soy, Wheat Cross Contact	Potential cross contact with other allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
Cumin	B	Micro sensitive ingredient (Bacillus cereus, Clostridium botulinum, C. perfringens, E.coli, Salmonella)	Product is harvested directly from the field	3	B	HIGH	Yes Supplier Approval	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Pesticides and Herbicides Residues	Farm practices not implemented	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Soy, Wheat Cross Contact	Potential cross contact with other allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
Coriander	B	Micro sensitive ingredient (Bacillus cereus, Clostridium botulinum, C. perfringens, E.coli, Salmonella)	Product is harvested directly from the field	3	B	HIGH	Yes Supplier Approval	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Pesticides and Herbicides Residues	Farm practices not implemented	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Soy, Wheat Cross Contact	Potential cross contact with other allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
Mustard Seed	B	Micro sensitive ingredient (Bacillus cereus, Clostridium botulinum, C. perfringens, E.coli, Salmonella)	Product is harvested directly from the field	3	B	HIGH	Yes Supplier Approval	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Pesticides and Herbicides Residues	Farm practices not implemented	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Soy, Wheat Cross Contact / Mustard considered an allergen in Canada	Potential cross contact with other allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
Caraway Seeds	B	Micro sensitive ingredient (Bacillus cereus, Clostridium botulinum, C. perfringens, E.coli, Salmonella)	Product is harvested directly from the field	3	B	HIGH	Yes Supplier Approval	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Pesticides and Herbicides Residues	Farm practices not implemented	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Soy, Wheat Cross Contact	Potential cross contact with other allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
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Whiskey	B	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	P	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	C	Gluten	Some alcoholic beverages are grain based and may contain wheat	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Almonds and nuts used for flavoring	Some Whiskeys utilize nuts for flavor	4	D	LOW	Yes	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Soy, Wheat Cross Contact	Potential cross contact with other allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Kosher Salt	B	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
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Sriracha Chili Sauce / Spices	B	Micro sensitive ingredient (E.coli, Salmonella)	Product is manufactured	3	D	HIGH	Yes Supplier Approval	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Soy, Wheat Cross Contact	Potential cross contact with other allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Frozen Roasted Garlic Puree	B	Micro sensitive ingredient (E.coli, Salmonella)	Product is manufactured	3	D	HIGH	Yes Supplier Approval	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	P	Presence of hazardous extraneous material	Normal manufacturing process presents minimal risk of physical hazards of concern.	4	D	LOW	No	Unlikely to occur since HRPC assessed and controlled at supplier.	Approved Supplier Program
	C	Soy, Wheat Cross Contact	Potential cross contact with other allergenic materials	3	B	HIGH	Yes Supplier	Allergen Cross Contact is Known to Occur	Approved Supplier Program

Ingredient	Hazard Category	Potential Hazard	Cause of Potential Hazard	Severity (1-6)	Frequency (A-E)	Risk Score See Table 2.4.3D	FSMA preventive control req'd? (Yes/No, Where)	Comments on Frequency Decision	Control Measures
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APPROVED			
Signature on File?	NAME	TITLE	DATE
x	Don Asplin	Consultant	10/18/17

CHANGE CONTROL			
CHANGE	REASON	NAME	DATE
	New Policy	Don Asplin	10/18/17
Added Frozen Garlic Puree	New supplier	Luke Visnic	9/20/18
Update control measures	10.5.18 Educational GMP	Luke Visnic	10/8/18

2.4.3F - PROCESS RISK ANALYSIS

LEGEND

B - Biological Hazards include bacteria, viruses & environmental pathogens.

C - Chemical Hazards include food allergens, substances such as pesticides & drug residue, natural toxins, radiological, decompositions & unapproved food colors and/or additives.

P - Physical Hazards include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

Processing Step	Hazard Category	Potential Hazard	Responsible for Risk:			Severity (1-6)	Frequency (1-5)	RISK Score See Table 2.2.4D	Control Measures	Control Measure this step?	
			Supplier	Plant	Cause					Yes	No
Section: 1 Step: 1 REFRIGERATED RAW MATERIAL RECEIVING	B	E-coli, Salmonella, Listeria Shigella spp, Clostridium botulinum, Giardia lamblia, S. aureus	X		Known pathogens associated with vegetables & animals from the field, including food fraud	3	B	HIGH	Approved Supplier Program	X	
	B	Materials exposed to excessive heat	X		Vegetable exposed to high temperature can support pathogens	3	B	HIGH	Approved Supplier program, Temperature Control Validation	X	
	P	Presence of hazardous extraneous material	X		Presence of metal and non-metallic materials	3	B	HIGH	Approved Supplier Program, Metal Detection	X	
	C	Pesticide levels	X		Pesticide levels due to poor agricultural practices	4	D	LOW	Approved Supplier Program	X	
	C	Undeclared Allergens	X		Undeclared allergens may be present in vegetable	3	B	HIGH	Approved Supplier Program (responsible to ensure allergens are not present in vegetables)	X	

Processing Step	Hazard Category	Potential Hazard	Responsible for Risk:			Severity (1-6)	Frequency (1-5)	RISK Score See Table 2.2.4B	Control Measures	Control Measure this step?	
			Supplier	Plant	Cause					Yes	No

Section 1 Step: 2 REFRIGERATED RAW MATERIAL STORAGE	B	Listeria, salmonella from refrigerated storage		X	Refrigeration units if not properly maintained can become a source of listeria contamination	4	D	LOW	Sanitation Program	X	
	B	Biological contamination due to improper handling by associates		X	Improper GMP's by associates can contribute to the contamination of foods	3	D	MEDIUM	GMP Training	X	
	P	NONE	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	C	NONE	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Section: 2 Step: 1 SALT & SPICE RECEIVING	B	Bacillus cereus, Salmonella from the field	X		Known pathogens associated with spices	3	B	MEDIUM	Approved Supplier Program	X	
	P	Presence of hazardous extraneous material	X		Presence of metal and non-metallic materials	3	B	HIGH	Approved Supplier Program, Metal Detection	X	
	C	NONE	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Processing Step	Hazard Category	Potential Hazard	Responsible for Risk:			Severity (1-6)	Frequency (1-5)	RISK Score See Table 2.2.4D	Control Measures	Control Measure this step?	
			Supplier	Plant	Cause					Yes	No
Section: 2 Step: 2 SALT & SPICE STORAGE	B	Spices not used in a timely manner		X	Stock Rotation First-In First-out or First expired first used	4	D	LOW	Sanitation Program	X	
	B	Biological contamination due to improper handling by associates		X	Improper GMP's by associates can contribute to the contamination of foods	3	D	MEDIUM	GMP Training	X	
	P	NONE	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	C	NONE	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Processing Step	Hazard Category	Potential Hazard	Responsible for Risk:			Severity (1-6)	Frequency (1-5)	RISK Score See Table 2.2.4D	Control Measures	Control Measure this step?	
			Supplier	Plant	Cause					Yes	No
Section: 3 Step: 1 FROZEN MATERIAL RECEIVING	B	E-coli, Salmonella, Listeria Shigella spp, Clostridium botulinum, Giardia lamblia, S. aureus	X		Known pathogens associated with vegetables & animals from the field, including food fraud	3	B	HIGH	Approved Supplier Program	X	
	B	Materials exposed to excessive heat	X		Vegetable exposed to high temperature can support pathogens	3	B	HIGH	Approved Supplier program, Temperature Control Validation	X	
	P	Presence of hazardous extraneous material	X		Presence of metal and non-metallic materials	3	B	HIGH	Approved Supplier Program, Metal Detection	X	
	C	Pesticide levels	X		Pesticide levels due to poor agricultural practices	4	D	LOW	Approved Supplier Program	X	
	C	Undeclared Allergens	X		Undeclared allergens may be present in vegetable	3	B	HIGH	Approved Supplier Program (responsible to ensure allergens are not present in vegetables)	X	

Processing Step	Hazard Category	Potential Hazard	Responsible for Risk:			Severity (1-6)	Frequency (1-5)	RISK Score See Table 2.2.4B	Control Measures	Control Measure this step?	
			Supplier	Plant	Cause					Yes	No
Section: 3 Step: 2 FROZEN RAW MATERIAL STORAGE	B	Listeria, salmonella from frozen storage		X	Refrigeration units if not properly maintained can become a source of listeria contamination	4	D	LOW	Sanitation Program	X	
	B	Biological contamination due to improper handling by associates		X	Improper GMP's by associates can contribute to the contamination of foods	3	D	MEDIUM	GMP Training	X	
	P	NONE	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	C	NONE	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Section: 4 Step: 1 PACKAGING RECEIVING	B	NONE	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	P	NONE	X		N/A	N/A	N/A	N/A	N/A	N/A	N/A
	C	Incorrect chemical composition for film	X		Chemical contamination is known to occur from packaging	4	D	LOW	Approved Supplier Program	X	
	C	Film or labels improperly printed	X		Undeclared allergens or mis-prints	4	D	LOW	Allergen Control Program	X	

Processing Step	Hazard Category	Potential Hazard	Responsible for Risk:			Severity (1-6)	Frequency (1-5)	Risk Score See Table 2.2.4D	Control Measures	Control Measure this step?	
			Supplier	Plant	Cause					Yes	No
Section: 4 Step: 2 PACKAGING STORAGE	B	Rodent, bird, insect contamination		X	Pests are associated with packaging contamination	4	E	LOW	Pest Management	X	
	P	NONE	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	C	NONE	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Section: 5 Step: 1 MATERIAL PREPARATION	B	Poor GMP practices		X	Poor handling procedures could contaminate the raw materials	3	D	MEDIUM	GMP Training	X	
	P	Non-metal contamination from packaging		X	Packaging material could remain after opening material packaging	3	D	MEDIUM	Foreign Material Program	X	
	C	Chemical residues remaining on equipment surfaces after cleaning		X	Chemical not properly rinsed or sanitizers not properly applied	3	D	MEDIUM	Sanitation Program	X	

Processing Step	Hazard Category	Potential Hazard	Responsible for Risk:			Severity (1-6)	Frequency (1-5)	RISK Score See Table 2.2.4D	Control Measures	Control Measure this step?	
			Supplier	Plant	Cause					Yes	No

Section: 5 Step: 2 MATERIAL SCALING & WEIGHING	B	Poor GMP practices		X	Poor handling procedures could contaminate the raw materials	3	D	MEDIUM	GMP Training	X	
	P	Non-metal contamination from packaging		X	Packaging material could remain after opening material packaging	3	D	MEDIUM	Foreign Material Program	X	
	C	Chemical residues remaining on equipment surfaces after cleaning		X	Chemical not properly rinsed or sanitizers not properly applied	3	D	MEDIUM	Sanitation Program	X	

Section: 5 Step: 3 MIXING	B	Contamination from handling practices		X	Improper handling could contaminate material	3	D	MEDIUM	GMP Training	X	
	P	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	C	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Section: 5 Step: 4 BARREL FERMENTER FILLING	B	Barrels not properly cleaned and sanitized		X	Barrels not properly cleaned and sanitized	4	D	LOW	Sanitation Program	X	
	P	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	C	Chemical residues remaining inside		X	Barrels not properly rinsed	4	D	LOW	Sanitation Program	X	

Processing Step	Hazard Category	Potential Hazard	Responsible for Risk:			Severity (1-6)	Frequency (1-5)	RISK Score See Table 2.2.4D	Control Measures	Control Measure this step?	
			Supplier	Plant	Cause					Yes	No
Section: 5 Step: 5 FERMENTATION (3-4 WEEKS)	B	Inadequate fermentation, elevated temperatures could lead to pathogen growth		X	Elevated temps could support pathogen growth Staphylococcus aureus, Clostridium botulinum	4	D	LOW	Temperature Control Validation	X	
	P	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	C	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Section: 6 Step: 1 HARVESTING & TESTING CRITICAL CONTROL POINT: pH VERIFICATION PROGRAM	B	Inadequate fermentation, elevated pH could lead to pathogen growth / Clostridium botulinum, E.coli, Salmonella, L. Monocytogenes		X	elevated pH levels could support pathogen growth Staphylococcus aureus, Clostridium	3	B	HIGH	CCP # 1 Ph Control Program	X	
	P	Potential for Foreign Material to be introduced		X	Foreign material from personnel may contaminate material	4	D	LOW	GMP Training	X	
	C	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Processing Step	Hazard Category	Potential Hazard	Responsible for Risk:			Severity (1-6)	Frequency (1-5)	RISK Score See Table 2.2.4D	Control Measures	Control Measure this step?	
			Supplier	Plant	Cause					Yes	No

Section: 6 Step: 2 LIQUID DRAINING	B	Contamination from handling practices		X	Improper handling could contaminate material	3	D	MEDIUM	GMP Training	X	
	P	Potential for Foreign Material to be introduced		X	Foreign material from personnel may contaminate material	4	D	LOW	GMP Training	X	
	C	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Section: 6 Step: 2a LIQUID REFRIGERATED STORAGE	B	Elevated temperatures could lead to pathogen growth		X	Elevated temps could support pathogen growth Staphylococcus aureus, Clostridium	4	D	LOW	Temperature Control Validation	X	
	P	Potential for Foreign Material to be introduced		X	Foreign material from personnel may contaminate material	4	D	LOW	GMP Training	X	
	C	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Processing Step	Hazard Category	Potential Hazard	Responsible for Risk:			Severity (1-6)	Frequency (1-5)	RISK Score See Table 2.2.4D	Control Measures	Control Measure this step?	
			Supplier	Plant	Cause					Yes	No
Section: 6 Step: 3 PACKING & DOSING	B	Improper handling of materials cross contamination		X	Material can support pathogen growth if contaminated	3	C	HIGH	GMP Training	X	
	B	Pathogen growth potential		X	Material can support pathogen growth if exposed to ambient temperature for over 12 hours during packaging	3	C	HIGH	Product refrigerated if not packaged within 8 hours.	X	
	P	Potential for Foreign Material to be introduced		X	Foreign material from personnel contaminate material	4	D	LOW	GMP Training	X	
	C	Chemical residues remaining after sanitation		X	Chemicals not properly rinsed after sanitation	3	D	MEDIUM	Sanitation Program	X	
	C	Contamination from the environment		X	Environmental program not controlling pathogens	3	D	MEDIUM	Sanitation Program	X	

Processing Step	Hazard Category	Potential Hazard	Responsible for Risk:			Severity (1-6)	Frequency (1-5)	RISK Score See Table 2.2.4D	Control Measures	Control Measure this step?	
			Supplier	Plant	Cause					Yes	No
Section: 6 Step: 4 CLEAN PACKAGE	B	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	P	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	C	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Section: 6 Step: 5 BAND SEALER	B	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	P	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	C	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Section: 6 Step: 6 METAL DETECTING	B	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	P	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	C	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Section: 6 Step: 6 LOT & DATE CODING	B	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	P	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	C	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Section: 6 Step: 6 CASING & PALLETIZING	B	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	P	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	C	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Section: 7 Step: 1 REWORK	B	NONE	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	P	NONE	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	C	NONE	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Processing Step	Hazard Category	Potential Hazard	Responsible for Risk:			Severity (1-6)	Frequency (1-5)	RISK Score See Table 2.2.4B	Control Measures	Control Measure this step?	
			Supplier	Plant	Cause					Yes	No
Section: 8 Step: 1 REFRIGERATED STORAGE (ON SITE)	B	Pathogenic growth due to inappropriate storage temperatures		X	Storage temperatures that exceed 35-40 degrees can support pathogenic growth	3	C	HIGH	Temperature Control Validation	X	
	P	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	C	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Section 8 Step: 2 REFRIGERATED WAREHOUSING (NATIONAL FREEZER)	B	Pathogenic growth due to inappropriate storage temperatures	X		Storage temperatures that exceed 35-40 degrees can support pathogenic growth	3	C	HIGH	Temperature Control Validation, Approved Supplier Program	X	
	P	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	C	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Section 8 Step: 3 REFRIGERATED TRANSPORT	B	Pathogenic growth due to inappropriate storage temperatures		X	Storage temperatures that exceed 35-40 degrees can support pathogenic growth	3	C	HIGH	Temperature Control Validation	X	
	P	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	C	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Processing Step	Hazard Category	Potential Hazard	Responsible for Risk:			Severity (1-6)	Frequency (1-5)	RISK Score See Table 2.2.4D	Control Measures	Control Measure this step?	
			Supplier	Plant	Cause					Yes	No

APPROVED			
Signature on File?	NAME	TITLE	DATE
x	Don Asplin	Consultant	10/18/17

CHANGE CONTROL			
CHANGE	REASON	NAME	DATE
	New Policy	Don Asplin	10/18/17
Revised for pouch packaging	New package	Luke Visnic	9/26/18
Update control measures & Step	Educ. Audit	Luke Visnic	10/8/18

CLEVELAND KRAUT
FLOW DIAGRAM for SAUERKRAUT PRODUCTS

