FOOD SAFETY PLAN: CANNED CHIPOTLE PEPPERS

COMPANY OVERVIEW

Empacadora del Golfo de México has a long history as a canner of vegetables and fruits. The firm's history began in the fall of 1940, when a group of investors from México City bought a small, family-run cannery and founded Empacadora del Golfo de México. After 77 years of hard work; it has become one of the largest vegetable canners in Mexico. Its brands "FARO", "JAROCHITA" and "LA COMADRE", are well known and preferred by the consuming public in most of México, large parts of the United States as well as in several other countries where the company is sending its products. Also, a large percentage of our sales are under our customer's private label.

We have the capacity to pack canned vegetables in: cans, pet jars, plastic bags, plastic buckets and plastic drums. Since March 2002, Empacadora del Golfo is operating in a new and modern food processing facility that will allow the company to grow over the next few years and adapt to the new demands of the market. Our product line includes green tomatillo, chipotle and serrano peppers, Mexican hot sauces and jalapeño peppers. Our brands have been the standard for flavor and quality in all markets where we compete for many years.

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PRODUCT DESCRIPTION

Products Names	Chipotle peppers in adobo sauce
Products Descriptions, including important food safety characteristic	It refers to dehydrated and smoked jalapeño chiles without healthy roots (chipotles), selected in dry, 7% of defects are accepted (toasted or of different tones). Chipotle peppers are hydrated with water and packed in tomato sauce. The product is packaged in hermetically sealed containers (tinplate) and processed thermally. The products are packaged in hermetically sealed containers (tinplate) and processed thermally. They are an acidified food with a pH at the final balance of 4.0 or less, with water activity (aw) greater than 0.85.
Ingredients	Chipotle Peppers, Water, Tomato Paste, Salt, Sugar, Onion, Acetic Acid.
Type of Packaging	Hermetic packaging (tin steel cans 603x700, 211x209x301)
Indications of use	After opening the container empties the contents in a container and refrigerate, it is consumed indirectly since it is used as an ingredient in the preparation of various foods.
Intended use	It is aimed at industrial customers or the Food Service for use in the production of different food products. Recommended for adults and children over 10 years old. Not recommended for people with medical restriction to irritating foods and with excess of sodium and sugar.
Shelf Life	Preferential consumption of 3 years.
Labeling instructions related to food safety	Store in a cool, dry place. Once opened refrigerate. Do not consume the food if the can is inflated.
Storage and distribution	Room temperature. Minimum recommendation 7 ° C, maximum 40 ° C in a clean and dry place.

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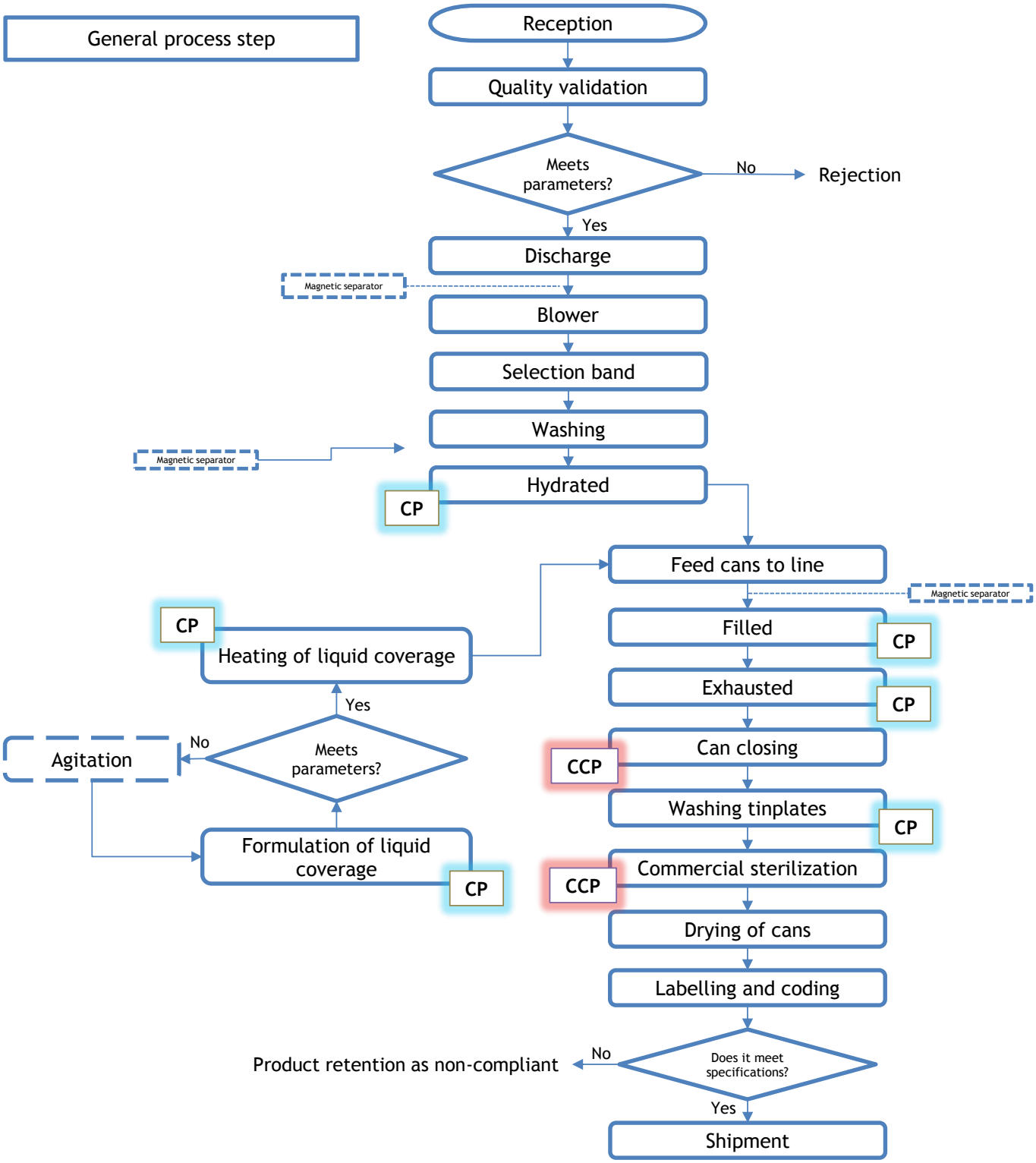
PROCESS FLOW CHART



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PROCESS NARRATIVE

Raw materials, Ingredients and Packaging Materials

Ingredients and raw materials are purchased from accredited suppliers who comply with international food safety and quality systems. All suppliers are subject to a review process prior to being authorized as reliable suppliers. Ingredients are stored according to the manufacturer's recommendations when these are specified.

Received Raw Materials

Raw materials	Suppliers / Manufacturer	Origin	Description
Chipotle Pepper (whole)	Guillermo Gómez (GU)	Mexico	Received in in yute bags of 30 kg.
Chipotle Pepper (whole)	Roberto Gómez (RO)	Mexico	Received in in yute bags of 30 kg.
Onion	Fernando Cayetano / Carlos Cayetano (MA)	Mexico	Received in plastic grid of 30 kg.
Salt (granules)	Industria Salinera de Yucatán (Comercial Salinera Roche, S.A. de C.V.)	Mexico	Received in110 pound polypropylene resin bags (50 kg) from our distributor. Specifications require food grade salt.
Acetic Acid (liquid)	Industrial Monfel S.A de C. V (INEOS Acetyls America)	United States	Received in 15-20 Ton capacity containers with security seals from our distributor.
Acetic Acid (liquid)	Pochteca Materias Primas, S.A. de C.V. (Celanese Chemical, Sekisui)	United States	Received in 15-20 Ton capacity containers with security seals from our distributor.
Acetic Acid (liquid)	Quimidroga S.A. (INEOS Acetyls UK Ltd)	United Kingdom	Received in 1ton capacity containers with security seals from our distributor.
Sugar (granules)	GRUPO PORRES S.A. (Ingenio Azucarero Modelo S.A. de C.V.)	Mexico	Received in 110 pound polypropylene resin bags (50 kg) from our distributor.
Sugar (granules)	Cargill de México, S.A. de C.V (Ingenio El Carmen S.A. de C.V.)	Mexico	Received in 110 pound polypropylene resin bags (50 kg) from our distributor.
Sugar (granules)	Cargill de México, S.A. de C.V (Ingenio San Cristobal S.A. de C.V.)	Mexico	Received in 110 pound polypropylene resin bags (50 kg) from our distributor.
Sugar (granules)	Grupo PROCOIMEX (Azucarera San José de Abajo S.A. de C.V.)	Mexico	Received in 110 pound polypropylene resin bags (50 kg) from our distributor.
Tomato paste (Paste)	BS Foods (Ingomar Packing Company LLC)	United States	Received in aseptic bag of 55 gallons, with polyethylene bags inside rolled steel packaging.
Tomato paste (Paste)	Productos Industrializados S.A de C.V	Mexico	Received in aseptic bag of 55 gallons, with polyethylene bags inside rolled steel packaging.
Tomato paste (Paste)	Sugal Chile Limitada	Chile	Received in aseptic bag of 55 gallons, with polyethylene bags inside rolled steel packaging.
Water	Veracruz Municipality	Mexico	Received at the storage well, sodium hypochlorite is added in the tank to achieve a free chlorine concentration of - 1.5 ppm in the production lines.

Received Packing

All packing materials are received in pallets and stacked. There are specifications of each product that guarantee that the packages that have direct contact with the product are made with food grade materials. The boxes are checked to verify that they meet the requirements and are free of allergenic ingredients of the product.

Storing Ingredients and Packaging

- Raw materials are processed as soon as they are received at the facility.
- Ingredients are stored according to supplier recommendations in a controlled area for access.
- Packaging is stored according to the supplier's recommendations in an exclusive area for packaging materials.

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PROCESS NARRATIVE

Steps of the process

Quality validation	The quality of the raw material, the ingredients and the packaging are verified before being downloaded. If they meet the quality parameters, the download is authorized.
Meets the parameters	Yes: if the raw material, the ingredients and the packaging comply with the parameters, the download is authorized No: the load is rejected.
Discharge	The unloading of raw materials takes place in the production area and the unloading of ingredients and packaging materials takes place in the finished product warehouse.
Blower	Blowing is carried out for the removal of foreign matter from the raw material.
Selection band	The selection of the chipotle peppers on a conveyor belt is performed, to remove the pieces out of specification.
Washing	The jalapeños are spray washed with chlorinated water (0.2 - 1.5 ppm).
Hydrated	The hydration is carried out in a specialized equipment (hydrator) with hot water and steam (T = 185°F - 194°F).
Feed tinplate to line	The containers are sent by means of a can transporter.
Formulation of liquid coverage	In the formulation area, the liquid is prepared according to the approved formulations manual, each batch of liquid prepared is verified in the quality assurance laboratory, if it complies with the %Ac, %Cl and pH parameters of the batch specification it is approved and if it does not comply with the parameters, it does not approve, perform the adjustment and verify again until the parameters fall within the specification.
Heating of liquid coverage	The cover liquid is heated to a temperature of T =185°F - 203°F.
Filled (hydrated product and liquid coverage)	The cans are filled with heavy hydrated product with calibrated scales, then they go through the addition of the covering liquid to acidify the product.
Exhausted	In this stage the product is subjected to a process of heating the product for a travel time of 1´03 min or 2'40 min (according to process line), to reach the closing temperature 176°-185°F acoording to the product.
Can closing	In the closure, the end of the container body is joined to its bottom or lid. The closure is obtained by bending the wing of the bottom around the flange of the body, hooking them together, to produce a tight connection.
Washing tinplate	At the exit of the closure the cans pass through a washing machine in which the washing of cans is carried out at a temperature of 158°-176.
Commercial sterilization	In commercial sterilization, products already hermetically sealed are subjected to thermal treatment at high temperature for a sufficient time to reduce the population of microorganisms and reduce the risk of toxin development. **Chipotle 6/10 :** Heating: 240°F - 243°F per 30 min in batch sterilization. **Chipotle 24/7:** Heating: 230°F to 233°F per 15 min in batch sterilization.
Drying of cans	Can drying is done to avoid oxidation of cans.
Labeling and coding	If the final product comply with the parameters of the specification, the labeling and coding of the product is released and continued according to the product identification system and traceability lotification AC-MP-COD-1.
Check finished product parameters	A physicochemical analysis of the finished product is performed 24 hours after production to determine its release or detection; Yes: released for storage, No: retention of the product as nonconforming.
Product detection as non-compliant	Quality management evaluates the nature of the non-conformity to consider the alternatives for the disposition of the units of non-conforming products and to decide what disposition will be taking.

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EMPACADORA DEL GOLFO DE MÉXICO

HAZARD ANALYSIS (INGREDIENTS AND PACKING MATERIAL)

Ingredient, packing material	Identify potential food safety hazards introduced, controlled or enhanced at this step		Risk evaluation (Is it a potential food safety hazard?)			Requires a preventive control?	Justify your decision for risk evaluation	What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?
			Impact	Likelihood	Impact x Likelihood			
Chipotle peppers	B	Presence of **pathogenic bacteria**: Salmonella, ECEH, Listeria Monocytogenes, C. Botulinum, Bacillus cereus, Presence of **viruses**: Norovirus, Hepatitis A, Presence of **parasites**: Cryptosporidium parvum, Cyclospora cayetanensis, Lamblia, Toxoplasma gondii, Trichinella spp.	Catastrophic	Likely	High	Yes	**Catastrophic:** Diseases caused by bacteria, viruses and parasites in food affect millions of people every year, sometimes with serious or fatal consequences. *Reference: WHO.* **Likely:** According to the FSPCA standardized curriculum, these microorganisms are the biological hazards of concern in fresh vegetables due to the history of food contamination found in the United States. Reference: FSPCA. According to the chemical characteristics of the product, the pathogenic bacteria that have growth at pH close to the product are Salmonella (3.7) and E. Coli (4.0). *Reference: FSPCA Ap4 Supplemental Information on Foodborne Pathogens.*	1. Supply chain: Supplier development. 2. Process Control (washing of the vegetable with chlorinated water, cooking, acidification of the product). 3. CCP2: Commercial sterilization.
Chipotle peppers	B	Presence of **molds:** Aspergillus	Critical	Ocassional	Medium High	Yes	**Critical:** Contaminated Aspergillus food is a cause of encephalopathy, seizures, paralysis, nystagmus, dystonia and spasmodic torticollis. *References: WHO.* **Ocassional:** According to health alert databases, in 2020 - 2021 there are multiple reports of mycotoxins outside the legal limits in dried chili peppers from the United Kingdom, India and Spain. *Reference: RASFF Database.*	1. Verification with analysis of the raw material
Chipotle peppers	C	Presence of **Heavy metals** above legal limits: Lead, Cadmium	Critical	Seldom	Medium High	Yes	**Critical:** If exposure to heavy metals in food is high, it can cause coma, convulsions and even death. *Reference: WHO.* **Seldom:** Lead and cadmium are chemicals that can be found in plants and crop soils as a result of treatments with pesticides based on these substances. In 2022, there is a food safety alert for red chili from Vietnam with concentrations greater than 0.02 mg/kg. There is a 5-year history of results for heavy metals in raw materials with results within legal limits. *Reference: RASFF Database.*	1. Supply chain: Supplier development 2. Verification of raw material by accredited laboratory analysis
Chipotle peppers	C	Presence of **Pesticides residues** above legal limits	Critical	Frecuent	High	Yes	**Critical:** Pesticide residues in high concentrations may have adverse health effects, e.g., cancer, reproductive, immune or nervous system consequences. *Reference: Health consequences of pesticide use in agriculture, WHO 1992.* **Frecuent:** According to databases, pesticide residues are one of the main food safety hazards in vegetables, in 2018 carbendazim residue was detected in canned Jalapeño peppers from Cuautitlan Izcalli, Mexico. In 2022, several food safety alerts were issued due to the presence of pesticides outside legal limits. *Reference: Red List FDA, RASFF Database.*	1. Supply chain: Supplier development 2. Verification of raw material by accredited laboratory analysis
Chipotle peppers	C	Development of Aflatoxins	Critical	Ocassional	Medium High	Yes	**Critical:** Aflatoxins are potent carcinogens that can affect any organ or system, and especially the liver and kidney; they cause liver cancer and have been linked to other types of cancer. aflatoxins are mutagenic (affect DNA) to bacteria, genotoxic, and can cause birth defects in children. *Reference: WHO.* **Ocassional:** According to health alert databases, in 2020 - 2021 there are multiple reports of mycotoxins outside the legal limits in dried chili peppers from the United Kingdom, India and Spain. *Reference: RASFF Database.*	1. Supply chain Verification with analysis of the raw material
Chipotle peppers	P	Presence of **foreign materia** (stones, wood, plastic, metal, glass)	Moderate	Seldom	Medium Low	No	**Moderate:** Depending on the size and shape of the object, it may cause choking, mouth injury or other adverse health effects. *Reference: FSPCA.* **Seldom:** The raw material comes from agricultural activities, so the presence of foreign matter such as stones or wood is possible, so there have been no complaints from customers about foreign matter coming from the fields.	1. Supply chain: Supplier development 2. Foreign matter removal equipment: Blower, magnetic separators 3. Step process: selection band
Onion	B	Presence of **pathogenic bacteria**: Salmonella, ECEH, Listeria Monocytogenes, C. Botulinum, Bacillus cereus, **Presence of viruses**: Norovirus, Hepatitis A, **Presence of parasites**: Cryptosporidium parvum, Cyclospora cayetanensis, Lamblia, Toxoplasma gondii, Trichinella spp.	Catastrophic	Likely	High	Yes	**Catastrophic:** Diseases caused by bacteria, viruses and parasites in food affect millions of people every year, sometimes with serious or fatal consequences. *Reference: WHO.* **Likely:** According to the FSPCA standardized curriculum, these microorganisms are the biological hazards of concern in fresh vegetables due to the history of food contamination found in the United States. Reference: FSPCA. According to the chemical characteristics of the product, the pathogenic bacteria that have growth at pH close to the product are Salmonella (3.7) and E. Coli (4.0). *Reference: FSPCA Ap4 Supplemental Information on Foodborne Pathogens.*	1. Supply chain: Supplier development. 2. Process Control (washing of the vegetable with chlorinated water, cooking, acidification of the product). 3. CCP2: Commercial sterilization.

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EMPACADORA DEL GOLFO DE MÉXICO

HAZARD ANALYSIS (INGREDIENTS AND PACKING MATERIAL)

Ingredient, packing material	Identify potential food safety hazards introduced, controlled or enhanced at this step		Risk evaluation (Is it a potential food safety hazard?)			Requires a preventive control?	Justify your decision for risk evaluation	What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?
			Impact	Likelihood	Impact x Likelihood			
Onion	C	Presence of **Heavy metals** above legal limits: Lead, Cadmium	Critical	Seldom	Medium High	Yes	**Critical:** If exposure to heavy metals in food is high, it can cause coma, convulsions and even death. *Reference: WHO.* **Seldom:** Lead and cadmium are chemicals that can be found in plants and crop soils as a result of treatments with pesticides based on these substances. There has been food safety alert for cadmium in onions 2015 in Italy. *Reference: RASFF data base.*	1. Supply chain: Supplier development 2. Verification of raw material by accredited laboratory analysis
Onion	C	Presence of **Pesticides Residues** above legal limits	Critical	Seldom	Medium High	Yes	**Critical:** Pesticide residues in high concentrations may have adverse health effects, e.g., cancer, reproductive, immune or nervous system consequences. *Reference: WHO.* **Seldom:** According to databases, pesticide residues are one of the main food safety hazards in vegetables, in 2021 propamocarb residue was detected in fresh onions from Cuapiaxtla, Mexico. In 2022, there is no record of food safety alerts for the presence of pesticides outside legal limits. *Reference: Red List FDA.*	1. Supply chain: Supplier development 2. Verification of raw material by accredited laboratory analysis
Onion	P	Presence of **foreign materia** (stones, wood, plastic, metal)	Moderate	Seldom	Medium Low	No	**Moderate:** Depending on the size and shape of the object, it may cause choking, mouth injury or other adverse health effects. *Reference: FSPCA.* **Seldom:** The raw material comes from agricultural activities, so it is possible the presence of foreign matter such as stones or wood, by history there are no reports of frequent foreign matter in vegetables.	1. Supply chain: Supplier development 2. Foreign matter removal equipment: Magnetic separators 3. Step process: Selection band
Salt	B	No significant food safety risk requiring preventive control is detected.						
Salt	C	Presence of **heavy metals** above legal limits: Lead, Mercury, Arsenic and Cadmium	Critical	Seldom	Medium High	Yes	**Critical:** If exposure to heavy metals in food is high, it can cause coma, convulsions and even death. *Reference: WHO.* **Seldom:** According to the databases, there is no frequent evidence of heavy metal contamination, however, due to its origin, there is a possibility of contamination, in 2011 there was a finding in Germany of mercury droplets in table salt. *Reference: RASFF Database.*	1. Supply chain: Supplier development 2. Verification of ingredient by accredited laboratory analysis
Salt	P	Presence of **foreign materia** (wood, glass, plastic, sea shells, metal)	Moderate	Seldom	Medium Low	No	**Moderate:** Depending on the size and shape of the object, it may cause choking, mouth injury or other adverse health effects. **Seldom:** According to food safety risk databases, there are 2 events due to the presence of foreign matter in the ingredient; 11/03/2021 Spain: plastic particles, 24/09/2020 United Kingdom: foreign body (wood pieces). *Reference: RASFF Database.*	1. Supply chain: Supplier development
Acetic acid	B	No significant food safety risk requiring preventive control is detected.						
Acetic acid	C	Presence of **heavy metals** above legal limits: Lead	Critical	Seldom	Medium High	Yes	**Critical:** If exposure to heavy metals in food is high, it can cause coma, convulsions and even death. *Reference: WHO.* **Seldom:** According to the databases, there is no frequent evidence of heavy metal contamination, however, due to its origin, there is a possibility of contamination. *Reference: FAO JECFA Monographs, INS No. 260.*	1. Supply chain: Supplier development 2. Verification of ingredient by accredited laboratory analysis
Acetic Acid	P	Presence of **foreign materia** (metal residues)	Moderate	Seldom	Medium Low	No	**Moderate:** Depending on the size and shape of the object, it may cause choking, mouth injury or other adverse health effects. *Reference: FSPCA.* **Seldom:** There has been only one event in 5 years of service due to the presence of metallic particles from poorly conditioned transport valves.The size of the detached particles is not a food safety hazard.	1. Supply chain: Supplier development
Acetic Acid	F	**Food Fraud**: Substance dilution, adulteration	Critical	Seldom	Medium High	Yes	**Critical:** Dilution may cause a change in the performance of the ingredient and will have direct consequences for the operation. **Seldom:** According to the food safety risk databases, only 1 event of acetic acid adulteration has been reported; 05/07/2010 Italy: adulteration (synthetic acetic acid) of white vinegar from Pakistan. *Reference: RASFF Database.*	1. Supply chain: Supplier development 2. Verification of concentration before the reception 3. Verification of ingredient by accredited laboratory analysis according to program
Sugar	B	Presence of **molds** en raw material: Aspergillus parasiticus	Critical	Seldom	Medium High	Yes	**Critical:** Consumption of moldy sugar cane can develop toxic encephalopathy, seizures, paralysis, nystagmus, dystonia and spasmodic torticollis. *References: Case Report ID 6374-6377 International Journal of Clinical and Experimental Medicine.* **Seldom:** There are reports of sugar cane deterioration in 2016 and 2017 in Egypt due to the presence of fungi. *Reference: RASFF data base.*	1. Supply chain: Supplier development

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HAZARD ANALYSIS (INGREDIENTS AND PACKING MATERIAL)

Ingredient, packing material	Identify potential food safety hazards introduced, controlled or enhanced at this step		Risk evaluation (Is it a potential food safety hazard?)			Requires a preventive control?	Justify your decision for risk evaluation	What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?
			Impact	Likelihood	Impact x Likelihood			
Sugar	C	Presence of **heavy metals** above legal limits: Lead, Arsenic	Critical	Seldom	Medium High	Yes	**Critical:** If exposure to heavy metals in food is high, it can cause coma, convulsions and even death. *Reference: WHO.* **Seldom:** According to the databases, there is no frequent evidence of heavy metal contamination, however, due to its origin, there is a possibility of contamination. *Reference: CODEX STAN 210 - 1999.*	1. Supply chain: Supplier development 2. Verification of ingredient by accredited laboratory analysis
Sugar	C	**Mycotoxin** growth: Arthrinium sp.	Critical	Seldom	Medium High	Yes	**Critical:** Ingestion of sugar contaminated with Arthrinium has as main clinical symptoms vomiting, dystonia, staring to one side, convulsions, carpopedal spasm and coma. *Reference: WHO.* **Seldom:** In the period from 1972 to 1988, a total of 884 people were involved in outbreaks of Arthrinium sp. in cane sugar in 13 provinces in northern China. *Reference: WHO.*	1. Supply chain: Supplier development 2. Verification of ingredient by accredited laboratory analysis (%humidity)
Sugar	C	Presence of **Pesticides Residues** above legal limits	Critical	Seldom	Medium High	Yes	**Critical:** Pesticide residues in high concentrations may have adverse health effects, e.g., cancer, reproductive, immune or nervous system consequences. *Reference: WHO.* **Seldom:** According to the databases, there is no frequent evidence of pesticides, however, due to its origin, there is a possibility of contamination. *Reference: Red List FDA.*	1. Supply chain: Supplier development 2. Verification of raw material by accredited laboratory analysis
Sugar	P	Presence of **foreign materia** (plastic, metal)	Moderate	Seldom	Medium Low	No	**Moderate:** Depending on the size and shape of the object, it may cause choking, mouth injury or other adverse health effects. *Reference: FSPCA.* **Seldom:** According to food safety risk databases, there are 1 event due to the presence of foreign matter in the ingredient; 2019 Belize: metal pieces. *Reference: RASFF Database.*	1. Supply chain: Supplier development
Tomato paste	B	Presence of **pathogenic bacteria**: Salmonella, ECEH, Listeria Monocytogenes, C. Botulinum, Bacillus cereus, Presence of **viruses**: Norovirus, Hepatitis A, Presence of **parasites**: Cryptosporidium parvum, Cyclospora cayetanensis, Lamblia, Toxoplasma gondii, Trichinella spp.	Catastrophic	Likely	High	Yes	**Catastrophic:** Diseases caused by bacteria, viruses and parasites in food affect millions of people every year, sometimes with serious or fatal consequences. *Reference: WHO.* **Likely:** According to the FSPCA standardized curriculum, these microorganisms are the biological hazards of concern in fresh vegetables due to the history of food contamination found in the United States. Reference: FSPCA. According to the chemical characteristics of the product, the pathogenic bacteria that have growth at pH close to the product are Salmonella (3.7) and E. Coli (4.0). *Reference: FSPCA Ap4 Supplemental Information on Foodborne Pathogens.*	1. Supply chain: Supplier development. 2. Process Control (washing of the vegetable with chlorinated water, cooking, acidification of the product). 3. CCP2: Commercial sterilization.
Tomato paste	C	Presence of **Heavy metals** above legal limits: Lead, Cadmium	Critical	Seldom	Medium High	Yes	**Critical:** If exposure to heavy metals in food is high, it can cause coma, convulsions and even death. *Reference: WHO.* **Seldom:** Lead and cadmium are chemicals that can be found in plants and crop soils as a result of treatments with pesticides based on these substances. *Reference: RASFF Database.*	1. Supply chain: Supplier development 2. Verification of raw material by accredited laboratory analysis
Tomato paste	C	Presence of **Pesticides residues** above legal limits	Critical	Likely	High	Yes	**Critical:** Pesticide residues in high concentrations may have adverse health effects, e.g., cancer, reproductive, immune or nervous system consequences. *Reference: Health consequences of pesticide use in agriculture, WHO 1992.* **Likely:** According to databases, pesticide residues are one of the main food safety hazards in vegetables, in 2020 methamidophos and acephate residues were detected in tomatoes from Zacatlán, Mexico. *Reference: Red List FDA, RASFF Database.*	1. Supply chain: Supplier development 2. Verification of ingredient by accredited laboratory analysis
Tomato paste	C	Presence of **Glycoalkaloids**: Tomatine	Moderate	Seldom	Medium Low	No	**Moderate:** In humans, the acute toxic effects of glycoalkaloids cause gastrointestinal symptoms such as nausea, vomiting and diarrhea from ingestion of glycoalkaloids in amounts of 1 mg/kg body weight or more. *Reference: WHO.* **Seldom:** Glycoalkaloids are usually present in leaves, stems and buds and in smaller amounts under the skin. it is necessary to remove the affected parts before cooking. *Reference: FAO.*	1. Supply chain: Supplier development
Tomato paste	F	**Food fraud**: Unauthorized color	Critical	Seldom	Medium High	Yes	**Critical:** Due to its high economic value and growing demand, tomato paste is considered a food at risk of food fraud. **Seldom:** According to food safety risk databases, there is 1 event due to the presence of unauthorized color in the ingredient; 2011 Poland. *Reference: RASFF Database.*	1. Supply chain: Supplier development

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Ingredient, packing material	Identify potential food safety hazards introduced, controlled or enhanced at this step		Risk evaluation (Is it a potential food safety hazard?)			Requires a preventive control?	Justify your decision for risk evaluation	What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?
			Impact	Likelihood	Impact x Likelihood			
Tomato paste	P	Presence of **foreign materia** (plastic, metal)	Moderate	Seldom	Medium Low	No	**Moderate:** Depending on the size and shape of the object, it may cause choking, mouth injury or other adverse health effects. *Reference: FSPCA.* **Seldom:** The raw material comes from agricultural activities, so it is possible the presence of foreign matter such as stones or wood, by history there are no reports of frequent foreign matter in vegetables.	1. Supply chain: Supplier development
Water	B	Presence of **pathogenic bacteria**: O157:H7	Critical	Seldom	Medium High	Yes	**Critical:** Symptoms of illness caused by Shiga toxin-producing E. coli include abdominal cramps and diarrhea, which may progress in some cases to bloody diarrhea (hemorrhagic colitis). Fever and vomiting may also be present. *Reference: WHO.* **Seldom:** E. coli O157:H7 may be found in water sources, such as private wells, that have been contaminated with feces from infected humans or animals. Waste can enter the water through different ways, including sewage overflows, sewage systems that are not working properly, polluted storm water runoff, and agricultural runoff. *Reference: Center for Disease Control and Prevention.*	1. Verification by accredited laboratory analysis 2. Process Control (water chlorination) 3. CCP2: Commercial sterilization
Water	C	Presence of **heavy metals** above legal limits; Aluminum, Arsenic, Barium, Cadmium, Copper, Lead, Iron, Manganese, Mercury, Zinc, Chromium	Critical	Seldom	Medium High	Yes	**Critical:** If exposure to heavy metals in food is high, it can cause coma, convulsions and even death. *Reference: WHO.* **Seldom:** Historical records show that the water is within specification for heavy metals	1. Verification by accredited laboratory analysis
Water	C	Presence of **radiation** above legal limits	Catastrophic	Improbable	Medium Low	No	**Catastrophic:** Exposure to low levels of radiation present in the environment does not cause immediate health effects, however it is a secondary general risk factor for cancer. *Reference: EPA.* **Improbable:** There is a Nuclear Power Plant in the state of Veracruz "Laguna Verde". Due to historical background, there have been no positive results for radiation in the water used for the process.	1. Verification by accredited laboratory analysis
Water	P	No significant food safety risk requiring preventive control is detected.						
Tin container	B	No significant food safety risk requiring preventive control is detected.						
Tin container	C	Chemical migration: Inorganic tin	Moderate	Seldom	Medium Low	No	**Moderate:** Only limited data is available on the toxicological effects of inorganic tin as present in canned foods, resultant from dissolution of the tin coating. The main potential hazard from acute ingestion seems to be gastric irritation in some individuals from exposure to high levels. *Reference: FAO.* **Seldom:** According to the food safety risk databases no recurrent food safety failures due to chemical migration in tinplate containers have been reported. *Reference: RASFF Database.*	1. Supply chain: Supplier development 2. Verification by accredited laboratory analysis
Tin container	P	No significant food safety risk requiring preventive control is detected.						
Cardboard to assemble boxes	B	No significant food safety risk requiring preventive control is detected.						
Cardboard to assemble boxes	C	No significant food safety risk requiring preventive control is detected.						
Cardboard to assemble boxes	P	No significant food safety risk requiring preventive control is detected.						
Tape for pasting boxes	B	No significant food safety risk requiring preventive control is detected.						
Tape for pasting boxes	C	No significant food safety risk requiring preventive control is detected.						
Tape for pasting boxes	P	No significant food safety risk requiring preventive control is detected.						
Storing ingredients and packaging	B	No significant food safety risk requiring preventive control is detected.						
Storing ingredients and packaging	C	No significant food safety risk requiring preventive control is detected.						
Storing ingredients and packaging	P	No significant food safety risk requiring preventive control is detected.						

FOOD SAFETY PLAN: CANNED CHIPOTLE PEPPERS

EMPACADORA DEL GOLFO DE MÉXICO

HAZARD ANALYSIS (PROCESSING STEP)

Processing Step	Identify potential food safety hazards introduced, controlled or enhanced at this step		Risk evaluation (Is it a potential food safety hazard?)			Requires a preventive control?	Justify your decision for risk evaluation	What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?
			Impact	Likelihood	Impact x Likelihood			
Reception	B	No significant food safety risk requiring preventive control is detected.						
Reception	C	No significant food safety risk requiring preventive control is detected.						
Reception	P	No significant food safety risk requiring preventive control is detected.						
Quality validation	B	No significant food safety risk requiring preventive control is detected.						
Quality validation	C	No significant food safety risk requiring preventive control is detected.						
Quality validation	P	No significant food safety risk requiring preventive control is detected.						
Discharge	B	No significant food safety risk requiring preventive control is detected.						
Discharge	C	No significant food safety risk requiring preventive control is detected.						
Discharge	P	No significant food safety risk requiring preventive control is detected.						
Blower	B	No significant food safety risk requiring preventive control is detected.						
Blower	C	No significant food safety risk requiring preventive control is detected.						
Blower	P	No significant food safety risk requiring preventive control is detected.						
Selection band	B	No significant food safety risk requiring preventive control is detected.						
Selection band	C	No significant food safety risk requiring preventive control is detected.						
Selection band	P	No significant food safety risk requiring preventive control is detected.						
Washing	B	No significant food safety risk requiring preventive control is detected.						
Washing	C	No significant food safety risk requiring preventive control is detected.						
Washing	P	No significant food safety risk requiring preventive control is detected.						
Hydrated	B	Survival of **pathogenic bacteria**; Salmonella, ECEH, Listeria Monocytogenes, Clostridium Botulinum, Bacillus cereus by insufficient heat treatment due to low temperature	Catastrophic	Seldom	Medium High	Yes	**Catastrophic:** Foods with high acidity are known to be susceptible to contamination by pathogenic bacteria. Diseases caused by pathogenic bacteria in food affect millions of people every year, sometimes with serious or fatal consequences. *Reference: WHO.* **Seldom:** A low initial temperature of the thermal process caused by temperature variations in process can lead to insufficient sterilisation, allowing pathogenic bacteria to survive. No recurrent variations in the scalding process due to process control history.	1. Preventive maintenance of equipment 2. Calibration of measuring instruments 3. Staff training 4. Monitoring of PC
Hydrated	B	Contaminación with **pathogenic bacteria** from the enviroment; Salmonella and Listeria Monocytogenes	Catastrophic	Improbable	Medium Low	No	**Catastrophic:** Diseases caused by bacteria, viruses and parasites in food affect millions of people every year, sometimes with serious or fatal consequences. *Reference: WHO.* **Improbable:** According to the chemical characteristics of the product, the development of Listeria Monocytogenes and Salmonella is not possible. Subsequent heat treatment is carried out.	1. GMP´s and sanitization procedures 2. CCP2: Commercial Sterilization
Hydrated	C	No significant food safety risk requiring preventive control is detected.						
Hydrated	P	No significant food safety risk requiring preventive control is detected.						
Feed tinplate line	B	No significant food safety risk requiring preventive control is detected.						
Feed tinplate line	C	No significant food safety risk requiring preventive control is detected.						
Feed tinplate line	P	No significant food safety risk requiring preventive control is detected.						

FOOD SAFETY PLAN: CANNED CHIPOTLE PEPPERS

EMPACADORA DEL GOLFO DE MÉXICO

HAZARD ANALYSIS (PROCESSING STEP)

Processing Step	Identify potential food safety hazards introduced, controlled or enhanced at this step		Risk evaluation (Is it a potential food safety hazard?)			Requires a preventive control?	Justify your decision for risk evaluation	What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?
			Impact	Likelihood	Impact x Likelihood			
Formulation of liquid coverage	B	Survival of **pathogenic bacteria**; Salmonella, ECEH, Listeria Monocytogenes, Clostridium Botulinum, Bacillus cereus	Catastrophic	Seldom	Medium High	Yes	**Catastrophic:** Foods with high acidity are known to be susceptible to contamination by pathogenic bacteria. Diseases caused by pathogenic bacteria in food affect millions of people every year, sometimes with serious or fatal consequences. *Reference: WHO.* **Seldom:** The acidity and salt concentrations of the brines are verified prior to their use in the production lines, historically there are no recurring deviations in the results obtained.	1. Procedures for making brines 2. Procedure for the analysis of coverage fluids 3. Cooking staff training 4. Verification of the pH in each batch of pre-prepared brine
Formulation of liquid coverage	B	Contaminación with **pathogenic bacteria** from the enviroment; Salmonella and Listeria Monocytogenes,	Catastrophic	Improbable	Medium Low	No	**Catastrophic:** Diseases caused by bacteria, viruses and parasites in food affect millions of people every year, sometimes with serious or fatal consequences. *Reference: WHO.* **Improbable:** According to the chemical characteristics of the product, the development of Listeria Monocytogenes and Salmonella is not possible. Subsequent heat treatment is carried out.	1. GMP´s and sanitization procedures 2. CCP2: Commercial Sterilization
Formulation of liquid coverage	C	Contaminación with preservatives (sulphites) or excessive concentrations of food additives	Moderate	Seldom	Medium Low	No	**Moderate:** Contamination of products by undeclared additives or ingredients or in excessive concentrations can generate a health impact and non-compliance with the legality of the product. *Reference: FDA.* **Seldom:** By history, there have been no findings of contamination from non-permitted additives or out-of-specification concentrations.	1. Formulation Manual 2. Review of ingredient inventories 3. Trained personnel 4. Restricted access to preparation areas to prevent untrained personnel from being in the process area
Formulation of liquid coverage	P	No significant food safety risk requiring preventive control is detected.						
Heating of liquid coverage	B	Survival of **pathogenic bacteria**; Salmonella, ECEH, Listeria Monocytogenes, Clostridium Botulinum, Bacillus cereus by insufficient heat treatment due to low temperature	Critical	Seldom	Medium High	Yes	**Critical:** Diseases caused by improperly treated food can be fatal. *Reference: WHO.* **Seldom:** A low initial temperature of the thermal process caused by temperature variations in process can lead to insufficient sterilisation, allowing pathogenic bacteria to survive. No recurrent variations in the heating of liquid coverage due to process control history.	1. Preventive maintenance of equipment 2. Calibration of measuring instruments 3. Staff training 4. Monitoring of PC
Heating of liquid coverage	C	No significant food safety risk requiring preventive control is detected.						
Heating of liquid coverage	P	No significant food safety risk requiring preventive control is detected.						
Filled (hydrated product and liquid coverage)	B	Survival of **pathogenic bacteria**; Salmonella, ECEH, Listeria Monocytogenes, Clostridium Botulinum, Bacillus cereus	Catastrophic	Seldom	Medium High	Yes	**Catastrophic:** Excess product inside the can and a lower volume of covering liquid may affect the transfer of the product and not acidify it correctly. Foods with high acidity are known to be susceptible to contamination by pathogenic bacteria. Diseases caused by pathogenic bacteria in food affect millions of people every year, sometimes with serious or fatal consequences. *Reference: WHO.* **Seldom:** According to the history, there are no recurring variations in the drained weight of the product that would pose a risk to the safety of the product.	1. The liquid of cover is added to the same level in all the cans, by means of a liquid aggregate 2. Monitoring of the masses drained during the process 3. It is verified that all cans carry the same level of liquid coverage
Filled (scalded product and liquid coverage)	B	Contaminación with **pathogenic bacteria** from the enviroment; Salmonella and Listeria Monocytogenes	Catastrophic	Improbable	Medium Low	No	**Catastrophic:** Diseases caused by bacteria, viruses and parasites in food affect millions of people every year, sometimes with serious or fatal consequences. *Reference: WHO.* **Improbable:** According to the chemical characteristics of the product, the development of Listeria Monocytogenes and Salmonella is not possible. Subsequent heat treatment is carried out.	1. GMP´s and sanitization procedures 2. CCP2: Commercial Sterilization
Filled (scalded product and liquid coverage)	C	No significant food safety risk requiring preventive control is detected.						
Filled (scalded product and liquid coverage)	P	No significant food safety risk requiring preventive control is detected.						
Exhausted	B	Survival of **pathogenic bacteria**; Salmonella, ECEH by insufficient heat treatment due to low temperature	Catastrophic	Seldom	Medium High	Yes	**Catastrophic:** Foods with high acidity are known to be susceptible to contamination by pathogenic bacteria. Diseases caused by pathogenic bacteria in food affect millions of people every year, sometimes with serious or fatal consequences. *Reference: WHO.* **Seldom:** According to the history, there are no recurring variations in the closure temperature of the product that would pose a risk to the safety of the product.	1. Preventive maintenance of equipment 2. Calibration of measuring instruments 3. Staff training 4. Monitoring of PC
Exhausted	C	No significant food safety risk requiring preventive control is detected.						
Exhausted	P	No significant food safety risk requiring preventive control is detected.						

HAZARD ANALYSIS (PROCESSING STEP)

Processing Step	Identify potential food safety hazards introduced, controlled or enhanced at this step		Risk evaluation (Is it a potential food safety hazard?)			Requires a preventive control?	Justify your decision for risk evaluation	What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?
			Impact	Likelihood	Impact x Likelihood			
Can closing	B	Recontamination with **pathogenic bacteria**: L. monocytogenes, pathogenic strains of E. coli, Salmonella spp., S. aureus, and B. cereus by a leak or loses seal integrity	Catastrophic	2	Medium High	Yes	**Catastrophic:** Due to poor closure and lack of tightness, there may be a subsequent contamination. The presence of pathogens bacteria can cause damage to the health of consumers and food degradation. *Reference: Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry* **Seldom:** According to the process control records, there are no frequent out-of-specification results, the historical microbiological results are absent of aerobic bacteria, molds and yeasts.	1. Adjust hooks and overlap at the start of production 2. Review of overlap every 1 1/2 hours (Monitoring) 3. Visual inspection of closures (Monitoring) 4. Preventive maintenance of equipment 5. Calibration of measuring instruments 6. Staff training 7. Monitoring of CCP
Can closing	C	No significant food safety risk requiring preventive control is detected.						
Can closing	P	No significant food safety risk requiring preventive control is detected.						
Washing tinplate	B	Survival of **pathogenic bacteria**; Salmonella, ECEH by insufficient heat treatment due to low temperature	Catastrophic	Seldom	Medium High	Yes	**Catastrophic:** Diseases caused by improperly treated food can be fatal. Reference: WHO. A low initial temperature of the thermal process caused by temperature variations in washing tinplate can lead to insufficient sterilisation, allowing pathogenic bacteria to survive. **Seldom:** According to the history, there are no recurring variations in the temperature of the tinplate wash water that pose a risk to the safety of the tinplate.	1. Preventive maintenance of equipment 2. Calibration of measuring instruments 3. Staff training 4. Monitoring of PC
Washing tinplate	C	No significant food safety risk requiring preventive control is detected.						
Washing tinplate	P	No significant food safety risk requiring preventive control is detected.						
Commercial sterilization	B	Survival of **pathogenic bacterias**; Bacillus cereus, spores of Bacillus coagulans and Clostridium pasterianum.	Catastrophic	Seldom	Medium High	Yes	**Catastrophic:** Application of an inadequate thermal process can guarantee the survival of microorganism. The presence of bacterias can cause damage to the health of consumers and food degradation. Reference: WHO. **Seldom:** According to the process control records, there are no frequent out-of-specification results, the historical microbiological results are absent of bacteria, molds and yeasts.	1. Operating procedures 2. Specific personnel and Training 3. Monitoring procedures 4. Calibration of measuring equipment 5. Preventive maintenance of equipment 6. Monitoring of CCP
Commercial sterilization	C	No significant food safety risk requiring preventive control is detected.						
Commercial sterilization	P	No significant food safety risk requiring preventive control is detected.						
Drying of cans	B	No significant food safety risk requiring preventive control is detected.						
Drying of cans	C	No significant food safety risk requiring preventive control is detected.						
Drying of cans	P	No significant food safety risk requiring preventive control is detected.						
Labeling and coding	B	No significant food safety risk requiring preventive control is detected.						
Labeling and coding	C	No significant food safety risk requiring preventive control is detected.						
Labeling and coding	P	No significant food safety risk requiring preventive control is detected.						

FOOD SAFETY PLAN: CANNED CHIPOTLE PEPPERS

EMPACADORA DEL GOLFO DE MÉXICO

PROCESS APPLIED PREVENTIVE CONTROLS PROGRAM

Preventive controls applied for process steps with a medium risk assessment or higher according to the hazard analysis.

PREVENTIVE CONTROLS (PC)										
Proccesing Step	Hazard		Critical Limits	Monitoring				Corrective Action	Verification	Records
				What	How	Frecuency	Who			
Hydrated	B	Survival of **pathogenic bacteria**; Salmonella, ECEH, Listeria Monocytogenes, Clostridium Botulinum, Bacillus cereu	185°F - 194°F	Hydrated temperature	The thermometer is visually monitored	When starting production Each 60 minutes during the process run	Quality Monitor	1. Stop the closing line until it reaches the temperature indicated, 2. If the deviation continues, stop the process and seek mechanical maintenance support.	Record review	Verification of CP and CCP (products with thermal process ACPC-PCC/1)
Formulation of liquid coverage	B	Survival of **pathogenic bacteria**; Salmonella, ECEH, Listeria Monocytogenes, Clostridium Botulinum, Bacillus cereus	pH: max 3.8, %Ac: 1.1 - 1.3, %Cl: 3.3 - 3.8	pH, %Ac, %Cl	Titration: Analysis of the brine (% of Cl and Ac) pH measurement with potentiometer	Each batch before to being used in the production line	Preparation area operators Quality Assurance Supervisor	1. Formulation adjustment, 2. Formulation validation.	Record review	Analysis of coverage fluids ACLC / 1
Heating of liquid coverage	B	Survival of **pathogenic bacteria**; Salmonella, ECEH, Listeria Monocytogenes, Clostridium Botulinum, Bacillus cereus	185°F - 194°F	Coverage liquid temperature	Visually monitored with a bimetallic thermometer, it is immersed in the preparation being heated without touching walls or bottom surfaces	When starting production Each 60 minutes during the process run	Quality Monitor	1. Stop the closing line until it reaches the temperature indicated, 2. If the deviation continues, stop the process and seek mechanical maintenance support.	Record review	Verification of CP and CCP (products with thermal process ACPC-PCC/1)
Filled (hydrated product)	B	Survival of **pathogenic bacteria**; Salmonella, ECEH, Listeria Monocytogenes, Clostridium Botulinum, Bacillus cereus	6/10: 695 g max 24/7: 48 g max	Drained weight added to each can	Monitoring of drained weights of the product by draining the food and weighing it on a calibrated scale	When starting production Each 60 minutes during the process run	Quality Monitor	1. They stop from the processing lines, 2. Excess product is manually removed from each can.	Record review	Verification of CP and CCP (products with thermal process ACPC-PCC/1)
Exhauster	B	Survival of **pathogenic bacteria**; Salmonella, ECEH	176°F - 185°F	Closing temperature	Visually monitored with a bimetallic thermometer, it is immersed in the product heated without touching walls or bottom surfaces	When starting production Each 60 minutes during the process run	Quality Monitor	1. The closure is stopped and the product is left inside the exhauster for the necessary time until it reaches the closure temperature, 2. The temperature is checked to continue the process	Record review	Verification of CP and CCP (products with thermal process ACPC-PCC/1)
Washing tinplate	B	Survival of **pathogenic bacteria**; Salmonella, ECEH	158°F -176°F	Water temperature	The thermometer is visually monitored	When starting production Each 60 minutes during the process run	Quality Monitor	1. Stop the closing line until it reaches the temperature indicated, 2. If the deviation continues, stop the process and seek mechanical maintenance support.	Record review	Verification of CP and CCP (products with thermal process ACPC-PCC/1)

PREVENTIVE CRITICAL CONTROLS (PCC)										
Proccesing Step	Hazard		Critical Limits	Monitoring				Corrective Action	Verification	Records
				What	How	Frecuency	Who			
Can Closure	B	Recontamination with **pathogenic bacteria**: L. monocytogenes, pathogenic strains of E. coli, Salmonella spp., S. aureus, and B. cereus	Overlap minimum 603x700: 0.035" 211x209x301: 0.035"	Overlap	Application of mathematical calculus:T= GC + GT+ CT - LCWhere:T: Overlap GC: Hook body GT: End hook CT: End plate thickness LC: Seam length All units of measure in inches	At the beginning of the process. Each 1.5 hours during production run. Each change on the can supplier specs. Each machine setting	Engargolado Maintenance Personnel	1. Inform to quality: a: Maintenance personnel validate the result with 3 cans of each head involved, if in 2 of them the deviation is repeated stop the line and make adjustment, if it is only 1 of them the process may continue. b: Quality will validate with 3 cans in the Video seam equipment. If the defect repeats, adjust the seamer. 2. In case of having made the adjustment, repeat a and b of point 1. The process will not be able to continue until the deviation is corrected. 3. Separate the product from the last effective revision until the moment of detection for re-sampling and report.	Record review	Seaming inspection register MT-PCC-EN01
			Accepted closures	Scratches closure defects	Visual monitoring according to procedure MT-PEN-02	At the beginning of the production run Each 30 minutes during the process run	Engargolado Maintenance Personnel	1. Stop the process line and make the adjustments to the seamer according to procedure MT-PEN-02. 2. Visual inspection and calculation of overlaps after the adjustments are made. 3. Separate the product from the last effective revision until the moment of detection.	Record review	Seams visual inspection register MT-PCC-EN02
Commercial Sterilization	B	Survival of microorganisms; Bacillus cereus, spores of Bacillus coagulans and Clostridium pasterianum.	6/10: 240°F - 243°F per 30 min 24/7: 230°F - 233°F per 15 min	Temperature and time	The thermometer is visually monitored. The measurement must be made in a vertical position at eye level. Time is monitored with a wall clock and a chronometer	At the beginning Each 3 minutes, 15 minutes	Retort operator	For temperature deviation below specification: 1. Steam valve adjustment 2. Identify the quantity of product affected and segregate it. For time deviation less than the specification: 1. In case of interrupted process, identify the quantity of product affected and segregate it. NOTE: Product manufactured with deviation shall be handled as Nonconforming product.	Record review	Retort thermal process registers PREL/9

FOOD SAFETY PLAN: CANNED CHIPOTLE PEPPERS

ALLERGEN APPLIED PREVENTIVE CONTROLS PROGRAM

Ingredient Allergen Identification

Raw material	Manufacturer	Food Allergens in Ingredients										Preventive Control
		Egg	Milk	Soy	Wheat	Tree Nut	Peanut	Fish	Shelfish	Sesame	Sulphites	
Chipotle pepper	Guillermo Gómez	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Chipotle pepper	Roberto Gómez	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Onion	Fernando Cayetano / Carlos Cayetano	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Tomato paste	Ingomar Packing Company LLC	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Tomato paste	Productos Industrializados S.A de C.V	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Tomato paste	Sugal Chile Limitada	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Salt	Industria Salinera de Yucatán	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Acetic Acid	INEOS Acetyls America	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Acetic Acid	Celanese Chemical, Sekisui	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Acetic Acid	INEOS Acetyls UK Ltd	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Sugar	Ingenio Azucarero Modelo S.A. de C.V.	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Sugar	Ingenio El Carmen S.A. de C.V.	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Sugar	Ingenio San Cristobal S.A. de C.V.	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Sugar	Azucarera San José de Abajo S.A. de C.V.	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)

Formulation Allergen Identification

Formulation	Area	Food Allergens in Formulation										Preventive Control
		Egg	Milk	Soy	Wheat	Tree Nut	Peanut	Fish	Shelfish	Sesame	Sulphites	
ABE	Kitchen room	No	No	No	No	No	No	No	No	No	No	None

Production line and brine preparation area Allergen Identification

Production Line	Are allergens used in surrounding areas?	Food allergens present in the area										Preventive Control
		Egg	Milk	Soy	Wheat	Tree Nut	Peanut	Fish	Shelfish	Sesame	Sulphites	
6/10 Line	No	No	No	No	No	No	No	No	No	No	No	None
Hybrid Line	No	No	No	No	No	No	No	No	No	No	No	None
1/2 Line	No	No	No	No	No	No	No	No	No	No	No	None
Blower area	No	No	No	No	No	No	No	No	No	No	No	None
Kitchen room	Yes	No	No	No	No	No	No	No	No	No	Yes	Tanks and manufacturing utensils exclusively for the preparation of sulfite and sulfite-free brines, separation of the storage area

Allergen Verification Listing

Product	Allergen Statement
Chipotle peppers in adobo sauce	Based on the identification of allergens in the raw materials, formulation, preparation and packaging areas, it is concluded that the listed products are allergen-free. The plant produces products with sensitive chemicals and we have the necessary controls to avoid cross contamination.

SANITATION APPLIED PREVENTIVE CONTROLS PROGRAM

Hygienic zoning

According to Appendix 6 of the FSPCA Standardized Curriculum, the following questionnaire is used to determine the need for hygienic zoning according to risk in the facilities.

Question	Answer	Justification
1. Does the product formulation have an intrinsic property that would kill the environmental pathogen of concern?	Yes	Chipotle peppers in adobo sauce are an acidified product with a pH lower than <4.6, so it does not deserve the implementation of environmental monitoring or microbiological verification. This product has no history of contamination by pathogens, since it is not among the foods that have presented outbreaks of Salmonella and L. monocytogenes. According to Manufacturers of LACF are not required to do environmental monitoring because they are exempt from subpart C with regard to microbiological hazards that are regulated under part 113 (21 CFR 117.5(d)). Reference: Low-Acid Foods Packaged in Hermetically Sealed Containers (LACF) Regulation and the FDA Food Safety Modernization Act: Guidance for Industry.
2. Is the product or ingredient associated with pathogen contamination?	-	
3. Does the product receive a validated process control designed to kill environmental pathogens?	-	
4. Is the product exposed to the environmental after the kill step and before packaging?	-	
5. Are ready-to-eat ingredients used to produce a ready-to-eat product?	-	
6. Does a refrigerated ready-to-eat product support the growth of Listeria monocytogenes?	-	
If an intrinsic property eliminates environmental pathogens (e.g., the high acidity levels of vinegar-based sauces), the situation may not warrant the implementation of hygienic zoning.		

Cleaning and Sanitation

Purpose	Frequency	Who	Procedure	Monitoring	Corrections	Records	Verification
Cleaning and disinfecting direct and indirect food contact surfaces is important to reduce cross contamination or recontamination of microorganisms that can affect quality and product safety.	Cleaning without chemical detergents: At the beginning of the process, before the meal time, during process stops, at the end of the shift, no more than 24 hours of continuous production. Cleaning with chemical detergents: According to established production, no more than 48 hours of continuous production. Desinfection: According to the established production, no more than 48 hours of continuous production.	Cleaning and sanitation team members, production line personnel.	According to cleaning SOPs.	Visual inspection of direct and indirect food contact surfaces after cleaning. Checking concentrations of cleaning chemicals.	If residues of dirt are observed on the equipment or structures, clean again. If the cleaning chemicals do not have the proper concentration, prepare a new solution.	PRLI/8-4, PRLI/8-2, PRLI/8-5, Cleaning record Lines, ACVL/01 Cleaning Validation Format, PRLI-42 Verification of concentration of cleaning solutions and sanitizers	Microbiological analysis of direct food contact surfaces with an external laboratory according to internal program.

FOOD SAFETY PLAN: CANNED CHIPOTLE PEPPERS

EMPACADORA DEL GOLFO DE MEXICO

SUPPLY CHAIN APPLIED PREVENTIVE CONTROLS PROGRAM

Preventive controls applied for process steps with a medium risk assessment or higher according to the hazard analysis.

PREVENTIVE CONTROLS (PC)										
Ingredient	Hazard		Critical Limits	Monitoring				Corrective Action	Verification	Records
				What	How	Frecuency	Who			
Chipotle pepper	B	Presence of pathogenic bacteria	Absence	Salmonella, O157:H7	Sending of irrigation water or fresh raw material samples to external certified laboratory	Annual	Approved Supplier	Resampling, if the result is positive On-site supplier audit and execution of corrective action plans	Review of the certificate of analysis sent by the external Laboratory	Certificate of Analysis
Chipotle pepper	B C	Presence of molds: Aspergillus Development of Aflatoxins	15% Humidity max Ref.: Journal Experimental short time production of aflatoxins by Aspergillus parasiticus in mixed feeds	Aspergillus and aflatoxins	Sending of chipotle samples to external certified laboratory	Annual	Approved Supplier	Resampling, if the result is positive On-site supplier audit and execution of corrective action plans	Review of the certificate of analysis sent by the external Laboratory	Certificate of Analysis
Chipotle pepper	C	Presence of Heavy metals above legal limits	Lead 0.1 mg/kg Cadmium 0.05 mg/kg Ref.: Codex Alimentarius Comission CF/14 INF/1 Contaminants and toxins	Lead & cadmium	Sending of ground and fresh raw material samples to external certified laboratory	Annual	Approved Supplier	Resampling, if the result is positive On-site supplier audit and execution of corrective action plans	Review of the certificate of analysis sent by the external Laboratory	Certificate of Analysis
Chipotle pepper	C	Presence of Pesticides residues above legal limits	According to eCFR Title 40: Protection of Environment PART 180, considering the following groups: Pepper, Pepper, non bell, Vegetable fruiting group 8, 8-10)	Pesticides residues	Sending of fresh raw material samples to external certified laboratory	Each crop and field	Food safety personnel	Resampling, if the result is positive On-site supplier audit and execution of corrective action plans	Review of the certificate of analysis sent by the external Laboratory	Certificate of Analysis
Onion	B	Presence of pathogenic bacteria	Absence	Salmonella, O157:H7	Sending of irrigation water or fresh raw material samples to external certified laboratory	Annual	Approved Supplier	Resampling, if the result is positive On-site supplier audit and execution of corrective action plans	Review of the certificate of analysis sent by the external Laboratory	Certificate of Analysis
Onion	C	Presence of Heavy metals above legal limits	Lead 0.1 mg/kg Cadmium 0.05 mg/kg Ref.: Codex Alimentarius Comission CF/14 INF/1 Contaminants and toxins	Lead & cadmium	Sending of ground and fresh raw material samples to external certified laboratory	Annual	Approved Supplier	Resampling, if the result is positive On-site supplier audit and execution of corrective action plans	Review of the certificate of analysis sent by the external Laboratory	Certificate of Analysis
Onion	C	Presence of Pesticides residues above legal limits	According to eCFR Title 40: Protection of Environment PART 180, considering the following groups: Crop Group 3. Bulb Vegetables, Onion green, onion dry bulb, onion freh, subgroups 3-07B, 3-07A	Pesticides residues	Sending of fresh raw material samples to external certified laboratory	Annual	Food safety personnel	Resampling, if the result is positive On-site supplier audit and execution of corrective action plans	Review of the certificate of analysis sent by the external Laboratory	Certificate of Analysis
Salt	C	Presence of heavy metals above legal limits	Lead: 2 mg/kg Mercury: 0.1 mg/kg Arsenic: 0.5 mg/kg Cadmium: 0.5 mg/kg Ref.: CODEX STAN 193-1995	Lead, Mercury, Arsenic and Cadmium	Sending of ingredient sample to external certified laboratory	Annual	Approved Supplier	Separation of the affected lot and destruction, Request corrective actions from the provider	Review of the certificate of analysis sent by the external Laboratory	Certificate of Analysis
Acetic acid	C	Presence of heavy metals above legal limits	Not more than 0.5 mg/kg Ref.: FAO JECFA INS No. 260	Lead	Sending of ingredient sample to external certified laboratory	Annual	Approved Supplier	Separation of the affected lot and destruction, Request corrective actions from the provider	Review of the certificate of analysis sent by the external Laboratory	Certificate of Analysis
Acetic Acid	F	Food Fraud: Substance dilution, adulteration	Not less than 99.5% Ref.: FAO JECFA INS No. 260	% concentration	Verification of % acidity using Food Chemical Codex analytical method	Each batch received	Material management personnel	Rejected of product, Request corrective actions from the provider	Sending of ingredient sample to external laboratory	Certificate of Analysis
Sugar	B	Presence of molds	0.06% Humidity max Ref.:NMX-F-084-SCFI-2004	% humidity	Sending of ingredient sample to external certified laboratory	Annual	Approved Supplier	Separation of the affected lot and destruction, Request corrective actions from the provider	Review of the certificate of analysis sent by the external Laboratory	Certificate of Analysis
Sugar	C	Presence of heavy metals above legal limits	Lead: 0.5 mg/kg Arsenic: 1.0 mg/kg Ref.:NMX-F-084-SCFI-2004	Lead, Arsenic	Sending of ingredient sample to external certified laboratory	Annual	Approved Supplier	Separation of the affected lot and destruction, Request corrective actions from the provider	Review of the certificate of analysis sent by the external Laboratory	Certificate of Analysis
Sugar	C	Mycotoxin growth	0.06% Humidity max Ref.:NMX-F-084-SCFI-2004	% humidity	Sending of ingredient sample to external certified laboratory	Annual	Approved Supplier	Separation of the affected lot and destruction, Request corrective actions from the provider	Review of the certificate of analysis sent by the external Laboratory	Certificate of Analysis

SUPPLY CHAIN APPLIED PREVENTIVE CONTROLS PROGRAM

Preventive controls applied for process steps with a medium risk assessment or higher according to the hazard analysis.

PREVENTIVE CONTROLS (PC)										
Ingredient	Hazard		Critical Limits	Monitoring				Corrective Action	Verification	Records
				What	How	Frecuency	Who			
Sugar	C	Presence of Pesticides residues above legal limits	According to eCFR Title 40: Protection of Environment PART 180	Pesticides residues	Sending of ingredient sample to external certified laboratory	Annual	Approved Supplier	Separation of the affected lot and destruction, Request corrective actions from the provider	Review of the certificate of analysis sent by the external Laboratory	Certificate of Analysis
Tomato paste	B	Presence of pathogenic bacteria	Absence	Salmonella, O157:H7	Sending of ingredient samples to external certified laboratory	Annual	Approved Supplier	Resampling, if the result is positive On-site supplier audit and execution of corrective action plans	Review of the certificate of analysis sent by the external Laboratory	Certificate of Analysis
Tomato paste	C	Presence of heavy metals above legal limits	Lead 0.1 mg/kg Cadmium 0.05 mg/kg Ref.: Codex Alimentarius Comission CF/14 INF/1 Contaminants and toxins	Lead & cadmium	Sending of ingredient sample to external certified laboratory	Annual	Approved Supplier	Separation of the affected lot and destruction, Request corrective actions from the provider	Review of the certificate of analysis sent by the external Laboratory	Certificate of Analysis
Tomato paste	C	Presence of Pesticides residues above legal limits	According to eCFR Title 40: Protection of Environment PART 180	Pesticides residues	Sending of ingredient sample to external certified laboratory	Annual	Approved Supplier	Separation of the affected lot and destruction, Request corrective actions from the provider	Review of the certificate of analysis sent by the external Laboratory	Certificate of Analysis
Water	B	Presence of pathogenic bacteria	Absence	E. Coli O157:H7	Sending of water samples to external certified laboratory	Annual	Food safety personnel	Resampling, if the result is positive execution of corrective action plans	Review of the certificate of analysis sent by the external Laboratory	Certificate of Analysis
Water	C	Presence of heavy metals above legal limits	Aluminum: 0.2, Arsenic: 0.01, Barium: 0.7, Cadmium: 0.003, Copper: 2.0, Chromium: 0.05, Lead: 0.01, Iron: 0.3, Manganese: 0.1, Mercury: 0.006, Zinc: 3.0 (mg/L) Ref.: Guidelines for Drinking water Quality, WHO	Aluminum, Arsenic, Barium, Cadmium, Copper, Lead, Iron, Manganese, Mercury, Zinc, Chromium	Sending of water samples to external certified laboratory	Annual	Food safety personnel	Resampling, if the result is again out of specification, execute corrective action plans, resample the possibly affected product and release it according to results.	Review of the certificate of analysis sent by the external Laboratory	Certificate of Analysis

RECALL PLAN

The food safety leader is in charge of maintaining the recall plan and keeps originals in the Food Safety and Quality Laboratory.

Implementation records and forms used in preventive controls include the following:

1. Process preventive controls:

• Process control record: ACAG/3 Control of chlorine concentration in water, MT-PCC-EN01 Seaming inspection register, MT-PCC-EN02 Seams visual inspection register, PREL/9 Retort thermal process registers, ACPC-PCC/1 Verification of control points and critical control points (products with thermal process), PREL/10 Line and Seamer Registration.

• Formulation control record: PRCO/1 Report of daily preparations and consumption in the brine room and kitchen, PRCO/2 Temperature control of covering liquids, Analysis of coverage fluids ACLC / 1.

• Cleaning record: PRLI/8-4, PRLI/8-2, PRLI/8-5, ACVL/01 Cleaning Validation Format

2. Supply chain program:

Certificates of analysis, Analysis results from external laboratories, Letters of guarantee.

3. Training records for qualified individuals (in personnel files):

External courses, evaluations, training lists.

ANNEX

RISK ASSESSMENT MATRIX

Probability of occurrences			Impact				
			Catastrophic	Critical	Moderate	Minor	Negligible
Definition	Meaning	Value	(A)	(B)	(C)	(D)	(E)
Frequent	• Occurs frequently • Will be continuously experienced unless action is taken to change events	5	5A	5B	5C	5D	5E
Likely	• Occurs less frequently if corrective action is taken • Documented through surveillance	4	4A	4B	4C	4D	4E
Occasional	• Occurs sporadically • Discovered through surveillance	3	3A	3B	3C	3D	3E
Seldom	• Unlikely to occur • Rarely, if ever, reported	2	2A	2B	2C	2D	2E
Improbable	• Highly unlikely to occur • Never previously reported	1	1A	1B	1C	1D	1E

- Risk is **High** for codes 5A, 5B, 5C, 4A, 4B, 3A
- Risk is **Medium High** for codes 5D, 5E, 4C, 3B, 3C, 2A, 2B
- Risk is **Medium Low** for codes 4D, 4E, 3D, 2C, 1A, 1B
- Risk is **Low** for codes 3E, 2D, 2E, 1C, 1D, 1E

Catastrophic (A)

- Regulatory / Compliance violations / issues
- Inability to validate data
- Withdrawal of product manufacturer
- Tainted product
- Materials breech
- Productions delays
- Technical miscommunications
- Security / confidentiality breeches

Critical (B)

- A non-compliance finding resulting in process, or operational degradation
- A security finding requiring immediate corrective action prior to continued operation
- Reoccurring violation of any safety regulation resulting in serious injury
- Production errors containing regulatory violations that pose direct consequence to the operation

Moderate (C)

- Security finding requiring a corrective action plan
- Production element errors that may pose indirect consequences to the operation

Minor (D)

- No regulatory action anticipated
- No compliance impact anticipated
- No evident security threat affected
- Minor errors in completed company policy & procedures
- Production error containing quality system and or opportunities for improvement

Negligible (E)

- No regulatory compliance violation
- No security confidentiality element affected
- On time production
- Validated experiments
- Clean product
- Properly executed communications

Reference: U.S. Department of Health & Human Services, Office of the Assistant Secretary for Preparedness and Response. Public Health Emergency Toolkit 2015.