

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.



Developed by: Adriana Cruzado Hernández, Food safety specialist COL November 2022

Approved: Mónica Núñez Rechy, Food Safety Manager PCQI, November 2022

Empacadora	del	Golfo de	México.	S.A.	de C.V	,
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Av. Framboyanes 1393, Cd. Ind. Bruno Pagliai, Zip 91697, Veracruz Ver, Mexico Phone 52 229 981 0614 Fax: 52 229 9 36 58 58, www.faro.com.mx FDA's FFR 10490143368, D-U-N-S Number 81-062-0575

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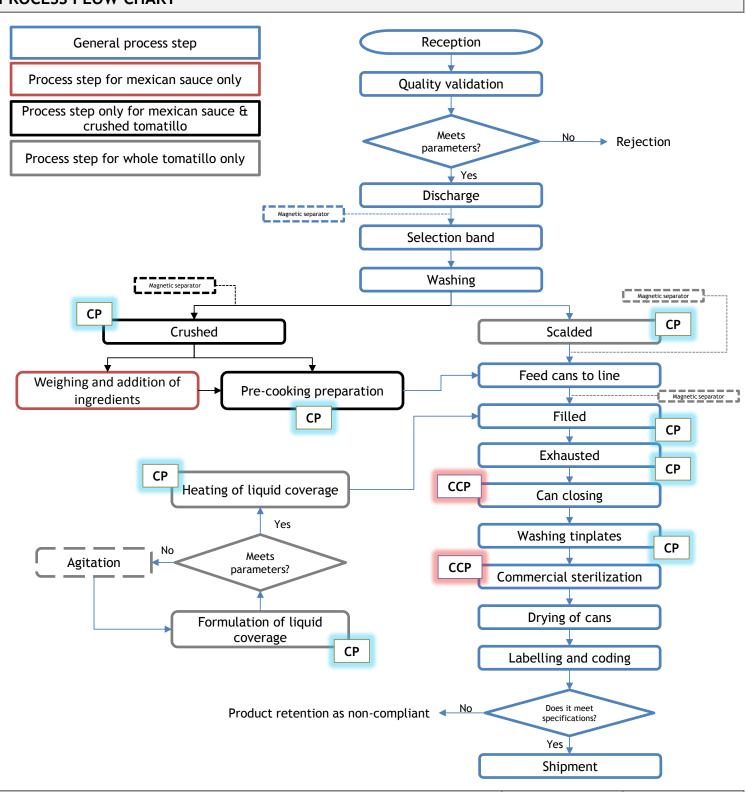
PRODUCT DESCRIPTION

Products Names	Whole Green Tomatillo, Crushed Green Tomatillo, Green Mexican Sauce						
	Whole Green Tomatillo: Refers to Whole Green Tomatillos, free of peel, firm texture and approximately 3.0 to 6.5 cm. in diameter.						
Products Descriptions,	Crushed Green Tomatillo: Refers to green tomatillos, healthy, ripe and clean, free of husk, which are subjected to a process of cutting cubes (1/8").						
•	Green Mexican Sauce: It refers to a blend of Green Tomatillos, Onion, Jalapeño Chili and Coriander, cut into cubes (1/8 ") 3 mixed with other ingredients according to the SVE formula described in the Formulation Manual.						
	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 3.5 or less for Whole Tomatillo, 4.0 or less for Crushed Tomatillo and 4.2 or less for Green Mexican Sauce, with water activity (aw) greater than 0.85.						
Ingredients	Green Tomatillos, Water, Onion, Jalapeño Peppers, Salt, Coriander, Garlic, Xanthan Gum, Citric Acid, Calcium Chloride.						
Type of Packaging	Hermetic packaging (tin steel cans 603x700)						
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.						
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 $^{\circ}$ C, maximum 40 $^{\circ}$ 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
Green tomatillo (whole)	Guillermo Gómez (GU)	Mexico	Received in plastic boxes of 30 kg
Green tomatillo (whole)	Efraín García (EF)	Mexico	Received in plastic boxes of 30 kg
Green tomatillo (whole)	Antonio Pimentel (AP)	Mexico	Received in plastic boxes of 30 kg
Green tomatillo (whole)	Benito Gómez (BE)	Mexico	Received in plastic boxes of 30 kg
Jalapeño Pepper (whole)	Guillermo Gómez (GU)	Mexico	Received in plastic grid of 30 kg.
Jalapeño Pepper (whole)	Roberto Gómez (RO)	Mexico	Received in plastic grid of 30 kg.
Jalapeño Pepper (whole)	Alfredo Gómez (AL)	Mexico	Received in plastic grid of 30 kg.
Jalapeño Pepper (whole)	Ignacio Oloarte (JO)	Mexico	Received in plastic grid of 30 kg.
Jalapeño Pepper (whole)	Antonio Pimentel (AP)	Mexico	Received in plastic grid of 30 kg.
Onion (whole)	Fernando Cayetano / Carlos Cayetano (MA)	Mexico	Received in plastic grid of 30 kg.
Coriander (whole)	Fernando Cayetano / Carlos Cayetano (MA)	Mexico	Received in bunches in bulk of 2 - 5 kg.
Garlic (powder)	La Grandeza de León	Mexico	Received in Kraft paper sacks and polyethylene bags of 11 pound (5 kg) from our distributor.
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.
Citric Acid (powder)	Pochteca Materias Primas, S.A. de C.V. Comercializadora Veyco, S.A. de C.V. (RZBC Juxian CO. LTD)	China	Received in 55 pounds (25 kg) polyethylene bag contained in carton from our distributor.
Citric Acid (powder)	Comercializadora Veyco, S.A. de C.V. Proveedor Int. de Químicos S.A. de C.V. (Weifang Ensign Industry CO. LTD)	China	Received in 55 pounds (25 kg) polyethylene bag contained in carton from our distributor.
Xanthan gum (pellets)	Pochteca Materias Primas, S.A. de C.V. Comercializadora Veyco, S.A. de C.V. Proveedor Int. de Químicos S.A. de C.V. (Shandong Fufeng Fermentation CO. LTD)	China	Received in 55 pounds (25 kg) polyethylene bag contained in carton from our distributor.
Calcium Chloride (pellets)	Pochteca Materias Primas, S.A. de C.V. (Industrias del Alcalí, S.A. de C.V.)	Mexico	Received in 55 pounds (25 kg) polyethylene bag contained in carton from our distributor.
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.



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.					
Selection band	The selection of the tomatillo 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).					
Crushed	It refers to the grinding of the tomatillo, jalapeño pepper, onion and coriander with 1/8" blades according to the product.					
Weighing and addition of ingredients	The ingredients are measured according to the specifications established in the formulation manual, then added to each preparation of crushed raw material.					
Pre-cooking preparation	The precooking (heating) of the prepared sauce is carried out in kettles, until reaching the temperature of the specification $176^{\circ}F$ - $185^{\circ}F$					
Scalded	Blanching is carried out in a blancher with hot water and steam (T = 176°F - 185°F), to inactivate enzymes, fix the color and soften the product to favor its subsequent packaging.					
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 = 194°F - 203°F.					
Filled (scalded product and liquid coverage)	Whole tomatillo: The cans are filled with blanched product by a drum filler with a reference weight and then go through the addition of the cover liquid to acidify the product. Mexican sauce and crushed tomatillo: Manual packing of cans with product according to a pre-established level for net weight and headspace compliance					
Exhausted	In this stage the product is subjected to a process of heating the product for a travel time of 2'40 min, to reach the closing temperature 176°-185°F according 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. Whole Green Tomatillo 6/10: Heating: 208.4° - 212°F per 8 min in continuous sterilization. Heating: 225°F - 228°F per 6 min in batch sterilization. Crushed Tomatillo & Mexican Sauce: Heating: 225°F - 228°F per 35 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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Ingredient, packing material	Iden	tify <u>potential</u> food safety hazards introduced,	Risk evaluation (Is it a potential food safety hazard?)			Requires a	Justify your decision for risk evaluation	What preventive control measure(s) can be applied to	
ingredient, packing material		controlled or enhanced at this step	Impact	Impact x Likelihood Impact x Likelihood		preventive control?	Justily your decision for risk evaluation	significantly minimize or prevent the food safety hazard?	
Green tomatillo	В	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. <i>Reference: WHO</i> . 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). <i>Reference: FSPCA Ap4 Supplemental Information on Foodborne Pathogens</i> .	2. Process Control (washing of the vegetable with chlorinated	
Green tomatillo	С	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: It is known that lead and cadmium are chemicals that could be found in plants and crops, because certain fields that were formerly orchards were treated with pesticides based on these chemicals. Reference: RASFF Database.	Supply chain: Supplier development Verification of raw material by accredited laboratory analysis	
Green tomatillo	С	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: Health consequences of pesticide use in agriculture, WHO 1992. Seldom: According to databases, pesticide residues are one of the main food safety hazards in vegetables, in 2018 acephate residue was detected in tomatillo from Puebla, Mexico. In 2022, there is no record of food safety alerts for the presence of pesticides outside legal limits. Reference: Red List FDA, RASFF Database.		
Green tomatillo	С	Development of glycoalkaloids; tomatina	Moderate	Remote	Medium Low	No	Moderate: Lack of ripening in the vegetable results in the development of glycoalkaloids, which have acute toxic effects causing gastrointestinal symptoms such as nausea, vomiting and diarrhea upon ingestion in amounts of 1 mg/kg body weight or more. In humans there is no evidence of health problems associated with repeated or long-term ingestion at doses less than 1 mg/kg. Reference: Spanish Agency for Food Safety and Nutrition, 2020. Remote: According to the history of raw material receipts in the last 3 years, there is not a high percentage of raw material rejection due to defects that imply lack of maturation of the vegetable, such as white, purple or yellow colorations.	Supply chain: Supplier development Inspection of raw material at reception and during processing	
Green tomatillo	Р	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.	Supply chain: Supplier development Foreign matter removal equipment: magnetic separators Step process: selection band	
Jalapeño Pepper	В	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.	3 CCP2: Commercial sterilization	
Jalapeño Pepper	С	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 alter for red chill 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.	Supply chain: Supplier development Verification of raw material by accredited laboratory analysis	
Jalapeño Pepper	С	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.		



	Ident	tify potential food safety hazards introduced,	Risk evaluation	(Is it a potential food	d safety hazard?)	Requires a		What preventive control measure(s) can be applied to	
Ingredient, packing material		controlled or enhanced at this step	Impact	Likelihood	Impact x Likelihood		Justify your decision for risk evaluation	significantly minimize or prevent the food safety hazard?	
Jalapeño Pepper	Р	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.		
Coriander	В	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.	Supply chain: Supplier development. Process Control (washing of the vegetable with chlorinated	
Coriander	с	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: It is known that lead and cadmium are chemicals that could be found in plants and crops, because certain fields that were formerly orchards were treated with pesticides based on these chemicals. Reference: RASFF Database.		
Coriander	С	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: Health consequences of pesticide use in agriculture, WHO 1992. Seldom: According to databases, pesticide residues are one of the main food safety hazards in vegetables, in 2017 chlorpyrifos, tebuconazole and flubendiamide residues were detected in fresh coriander from Puebla, Mexico. In 2022, there is no record of food safety alerts for the presence of pesticides outside legal limits. Reference: Red List FDA, RASFF Database.	Supply chain: Supplier development Verification of raw material by accredited laboratory analysis	
Coriander	Р	No significant food safety risk requiring preventive	control is detected.						
Onion	В	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.		
Onion	с	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.	Supply chain: Supplier development Verification of raw material by accredited laboratory analysis	
Onion	С	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.	Supply chain: Supplier development Werification 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.		
Salt	В	No significant food safety risk requiring preventive	control is detected.						
Salt	С	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.	Supply chain: Supplier development	



	Ident	dentify potential food safety hazards introduced, Risk ev		isk evaluation (Is it a potential food safety hazard?)		Requires a		What preventive control measure(s) can be applied to
Ingredient, packing material		controlled or enhanced at this step	Impact	Likelihood	Impact x Likelihood	preventive control?	Justify your decision for risk evaluation	significantly minimize or prevent the food safety hazard?
Salt	Р	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
Gartic	В	Presence of pathogenic bacteria : Salmonella, ECEH, C. Botulinum, Bacillus cereus, C. Perfringens	Catastrophic	Likely	High	Yes	Catastrophic: Diseases caused by bacteria 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 spices due to the history of food contamination found in the United States. Reference: Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls FDA. According to the chemical characteristics of the product, the pathogenic bacteria that have growth at pl close to the product are Salmonella (3.7) and E. Coli (4.0). Reference: FSPCA Ap4 Supplemental Information on Foodborne Pathogens.	2. Process Control (Heating or liquid coverage, acidification of the
Garlic	С	Presence of heavy metals above legal limits: Lead, Cadmium	Critical	Ocassional	Medium High	Yes	Critical: If exposure to heavy metals in food is high, it can cause coma, convulsions and even death. Reference: WHO. Occasional: According to the databases there are reports of Cadmium in garlic powder Netherlands 2021, Belgium 2020 and China 2020. Reference: RASFF Database.	Supply chain: Supplier development Verification with analysis of the finished product
Gartic	С	Mycotoxin growth: Ochratoxin A	Critical	Ocassional	Medium High	Yes	Critical: The most sensitive and noticeable effect is kidney damage, but the toxin may also have effects on fetal development and the immune system. Reference: WHO. Occasional: According to food safety risk databases there are reports of the presence of Ochratoxin A in 2016 and 2017 India. Reference: RASFF Database.	Supply chain: Supplier development
Garlic	С	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 garlic, in 2021 Benzo(a)pyrene was detected in wild garlic, Germany. In 2022, there is no record of food safety alerts for the presence of pesticides outside legal limits. Reference: Red List FDA.	
Garlic	Р	No significant food safety risk requiring preventive	control is detected.					
Citric acid	В	No significant food safety risk requiring preventive	control is detected.					
Citric acid	С	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. 330.	Supply chain: Supplier development Verification of ingredient by accredited laboratory analysis
Citric acid	P	No significant food safety risk requiring preventive	control is detected.					
Calcium Chloride	В	No significant food safety risk requiring preventive	control is detected.					
Calcium Chloride	С	Presence of heavy metals above legal limits: Magnesium, Fluoride, 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. 509.	Supply chain: Supplier development Verification of ingredient by accredited laboratory analysis
Calcium Chloride	С	Contamination with environmental pollutants : dioxins	Moderate	Seldom	Medium Low	No	Moderate: Dioxins are highly toxic and can cause reproductive and developmental problems, affect the immune system, interfere with hormones and thus cause cancer at high concentrations and constant exposure. Reference: WHO. Seldom: According to the food safety risk databases, only 1 event of dioxins contamination has been reported; 02/11/2018 Netherlands: dioxins in coated calcium chloride from Belgium, with raw material from China. Reference: RASFF Database	1. Supply chain: Supplier development
Calcium Chloride P No significant food safety risk requiring preventive control is detected.								



	Identify potential food safety hazards introduced,		Risk evaluation (Is it a potential food safety hazard?)			Requires a		What preventive control measure(s) can be applied to		
Ingredient, packing material		controlled or enhanced at this step	Impact	Likelihood	Impact x Likelihood	preventive control?	Justify your decision for risk evaluation	significantly minimize or prevent the food safety hazard?		
Xanthan gum	В	Presence of pathogenic bacteria : Salmonella spp.	Catastrophic	Improbable	Medium Low	No	Catastrophic: Diseases caused by bacteria in food affect millions of people every year, symptoms of salmonellosis include diarrhea, fever and abdominal pain. Reference: WHO. Improbable: It is known from literature that these microorganisms can be found in xanthan gum. Reference: Table 1C: Information that you should consider for potential ingredient or other food-related biological hazards for Food Additives. There are no reports of contamination of the ingredient with salmonella in various food safety databases in the last 2 years. Reference: RASFF Database, Recalls, Market Withdrawals, & Safety Alerts FDA, FAVV-AFSCA	Supply chain: Supplier development. CCP2: Commercial sterilization.		
Xanthan gum	С	Presence of Pesticides residues above legal limits	Critical	Ocassional	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. Occasional: In 2021 there were several reports of ethylene oxide in xanthan gum from China, Italy. Reference: RASFF Database	Supply chain: Supplier development Verification of raw material by accredited laboratory analysis		
Xanthan gum	Р	No significant food safety risk requiring preventive	control is detected.							
Water	В	Presence of pathogenic bacteria: 0157: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 0157: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.	Verification by accredited laboratory analysis Process Control (water chlorination) CCP2: Commercial sterilization		
Water	С	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	Verification by accredited laboratory analysis		
Water	С	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.	Verification by accredited laboratory analysis		
Water	Р	No significant food safety risk requiring preventive	control is detected.							
Tin container	В	No significant food safety risk requiring preventive	control is detected.							
Tin container	С	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.	Supply chain: Supplier development Verification by accredited laboratory analysis		
Tin container	Р	No significant food safety risk requiring preventive	control is detected.							
Cardboard to assemble boxes	В	No significant food safety risk requiring preventive	control is detected.							
Cardboard to assemble boxes	С	C No significant food safety risk requiring preventive control is detected.								
Cardboard to assemble boxes	Р	P No significant food safety risk requiring preventive control is detected.								
Tape for pasting boxes	В	No significant food safety risk requiring preventive								
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										
Storing ingredients and packaging	С	No significant food safety risk requiring preventive								
Storing ingredients and packaging	Р	No significant food safety risk requiring preventive	control is detected.							

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HAZARD ANALYSIS (PROCESSING STEP)

	Ident	cify potential food safety hazards introduced,	Risk evaluation	(Is it a potential foo	d safety hazard?)	Requires a		What preventive control measure(s) can be applied to
Processing Step	luein	controlled or enhanced at this step	Impact	Likelihood	Impact x Likelihood	preventive control?	Justify your decision for risk evaluation	significantly minimize or prevent the food safety hazard?
Reception	В	No significant food safety risk requiring preventive	control is detected.					
Reception	С	No significant food safety risk requiring preventive	control is detected.					
Reception	Р	No significant food safety risk requiring preventive	control is detected.					
Quality validation	В	No significant food safety risk requiring preventive	control is detected.					
Quality validation	С	No significant food safety risk requiring preventive	control is detected.					
Quality validation	Р	No significant food safety risk requiring preventive	control is detected.					
Discharge	В	No significant food safety risk requiring preventive	control is detected.					
Discharge	С	No significant food safety risk requiring preventive	control is detected.					
Discharge	Р	No significant food safety risk requiring preventive	control is detected.					
Selection band	В	No significant food safety risk requiring preventive	control is detected.					
Selection band	С	No significant food safety risk requiring preventive	control is detected.					
Selection band	Р	No significant food safety risk requiring preventive	control is detected.					
Washing	В	No significant food safety risk requiring preventive	control is detected.					
Washing		No significant food safety risk requiring preventive						
Washing		No significant food safety risk requiring preventive						
Crushed		No significant food safety risk requiring preventive						
Crushed		No significant food safety risk requiring preventive						
Crusiled	-	no significant rood surety risk requiring preventive	control is detected.	I			I	
Crushed	P	Contamination with foreign materia: pieces of metal by blades	Critical	Ocassional	Medium High	Yes	Critical: Hard or sharp objects are potential physical hazards and can cause: cuts to the mouth or throat damage to the intestines damage to teeth or gums. Reference: FSPCA. Occasional: There have been reports of FDA recalls caused by ruptured metal components, HEB; 2020, Kraft Heinz; 2018. Reference: Recalls, Market Withdrawals, & Safety Alerts FDA.	Blade check three times per shift Maintenance check list Magnetic separator
Weighing and addition of ingredients	В	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.	GMP's and sanitization procedures CCP2: Commercial Sterilization
Weighing and addition of ingredients	с	No significant food safety risk requiring preventive	control is detected.					
Weighing and addition of ingredients	Р	No significant food safety risk requiring preventive	e control is detected.					
Pre-cooking preparation	В	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 sterilization, allowing pathogenic bacteria to survive. No recurrent variations in the precooking process due to process control history.	1. Preventive maintenance of equipment 2. Calibration of measuring instruments 3. Staff training 4. Monitoring of PC
Pre-cooking preparation	В	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.	GMP's and sanitization procedures CCP2: Commercial Sterilization
Pre-cooking preparation	С	No significant food safety risk requiring preventive	control is detected.					
Pre-cooking preparation	Р	No significant food safety risk requiring preventive	control is detected.					
Scalded	В	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 sterilization, 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



HAZARD ANALYSIS (PROCESSING STEP)

Processing Step Scalded B		controlled or enhanced at this step Contaminación with pathogenic bacteria from	Impact	Likelihood	Impact v Likelihaad	preventive control?	Justify your decision for risk evaluation	-iifithi-i-i th- fdf-t. bd		
		Contaminación with nathogenic hacteria from		Impact Likelihood Impact x Likelihood				significantly minimize or prevent the food safety hazard?		
		the environment; 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.	GMP's and sanitization procedures CCP2: Commercial Sterilization		
Scalded C	. N	o significant food safety risk requiring preventive	control is detected.							
Scalded P	N	o significant food safety risk requiring preventive	control is detected.							
Feed tinplate line B	N	o significant food safety risk requiring preventive	control is detected.							
Feed tinplate line C	N	o significant food safety risk requiring preventive	control is detected.							
Feed tinplate line P	N	o significant food safety risk requiring preventive	control is detected.							
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.	GMP's and sanitization procedures 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.	Review of ingredient inventories Trained personnel		
Formulation of liquid coverage P	N	o 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.	3. Staff training		
Heating of liquid coverage C	N	o significant food safety risk requiring preventive	control is detected.							
Heating of liquid coverage P	N	o significant food safety risk requiring preventive	control is detected.							
Filled 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.	means of a liquid aggregate		
Filled 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.	GMP's and sanitization procedures CCP2: Commercial Sterilization		
Filled C	N	o significant food safety risk requiring preventive	control is detected.							
Filled P	N	o significant food safety risk requiring preventive	control is detected.							



HAZARD ANALYSIS (PROCESSING STEP)

Processing Step	Ider	ntify potential food safety hazards introduced,	Risk evaluation	(Is it a potential foo	d safety hazard?)	Requires a	Justify your decision for risk evaluation	What preventive control measure(s) can be applied to		
Processing Step		controlled or enhanced at this step	Impact	Likelihood	Impact x Likelihood	preventive control?	Justify your decision for risk evaluation	significantly minimize or prevent the food safety hazard?		
Exhausted	В	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.			
Exhausted	С	No significant food safety risk requiring preventive	control is detected.							
Exhausted	Р	No significant food safety risk requiring preventive	control is detected.							
Can closing	В	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	С	No significant food safety risk requiring preventive	control is detected.							
Can closing	Р	No significant food safety risk requiring preventive	control is detected.							
Washing tinplate	В	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.	Preventive maintenance of equipment Calibration of measuring instruments Staff training Monitoring of PC		
Washing tinplate	С	No significant food safety risk requiring preventive	control is detected.							
Washing tinplate	Р	No significant food safety risk requiring preventive	control is detected.							
Commercial sterilization	В	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.	Operating procedures Specific personnel and Training Monitoring procedures Calibration of measuring equipment Preventive maintenance of equipment Monitoring of CCP		
Commercial sterilization	С	No significant food safety risk requiring preventive	control is detected.		•					
Commercial sterilization	Р	No significant food safety risk requiring preventive	control is detected.							
Drying of cans	В	No significant food safety risk requiring preventive	control is detected.							
Drying of cans	С	No significant food safety risk requiring preventive	control is detected.							
Drying of cans	Р	No significant food safety risk requiring preventive	control is detected.							
Labeling and coding	В	No significant food safety risk requiring preventive	control is detected.							
Labeling and coding	С	No significant food safety risk requiring preventive	control is detected.							
Labeling and coding	Р	No significant food safety risk requiring preventive	control is detected.							

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PROCESS APPLIED PREVENTIVE CONTROLS PROGRAM

					NTIVE CONTROLS (PC)				
Proccesing Step	Hazard	Critical Limits	What	Monit	toring	Who	Corrective Action	Verification	Records
Crushed P	Contamination with foreign materia: pieces of metal by blades	Absence strange matter	Remains pieces of metal by blades	Review of blades in good condition, without breaks, during the process	At the beginning of the shift Each 3 hours Each shift changes In case of blade breakage	Line Operator	1. The line is stopped, 2. The quality control personnel is informed, 3. Checks that the missing metal parts are found, 4. The product affected or at risk of presence of foreign matter is destroyed, 5. The area and equipment are washed, checked before starting production.	Record review	Report breakage of glass, fragile or hard plastic, metal and other materials ACPV / 01 PREL-51 Mexican Sauce Record
Pre cooking B	Survival of pathogenic bacteria; Salmonella, ECEH, Listeria Monocytogenes, Clostridium Botulinum, Bacillus cereu	176'F - 185'F	Pre cooking temperature	Visually monitored with a bimetallic thermometer, it is immersed in the kettles with product		Quality Monitor	Adjust temperature with steam valve, 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)
Scalded B	Survival of pathogenic bacteria; Salmonella, ECEH, Listeria Monocytogenes, Clostridium Botulinum, Bacillus cereu	176'F - 185'F	Scalded temperature	The thermometer is visually monitored. The measurement must be made in a vertical position at eye level	When starting production Each 60 minutes during the process run	Quality Monitor	Open the Blancher's steam valve further to reach the indicated temperature, Verify the initial temperature of the product prior to the thermal process, 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: 2.0 max , %Ac & %Cl: 2.2 - 2.8	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		Formulation adjustment, 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	194'F - 203'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	Stop the closing line until it reaches the temperature indicated, 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 B	Survival of pathogenic bacteria; Salmonella, ECEH, Listeria Monocytogenes, Clostridium Botulinum, Bacillus cereus	Whole tomatillo 6/10: D.W: 1680 g max Sauces 6/10: N.W: 2850 g max	Drained or net weight	Monitoring of drained or net 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	They stop from the processing lines, 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	Whole tomatillo 6/10: 179.6°F - 185°F Sauces 6/10: 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	The closure is stopped and the product is left inside the exhauster for the necessary time until it reaches the closure temperature, 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	Stop the closing line until it reaches the temperature indicated, 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)

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PROCESS APPLIED PREVENTIVE CONTROLS PROGRAM

					PREVENTIVE	CRITICAL CONTROLS (PCC)				
Proccesing Step	ng Step Hazard Critical Limits Monitoring Monitoring				toring		Corrective Action	Verification	Records	
				What	How	Frecuency	Who			
Can Closure	В	Recontamination with pathogenic bacteria: L. monocytogenes, pathogenic strains of E. coli, Salmonella spp., S. aureus, and B. cereus	Overlap minimum 603x700: 0.035"	Overlap	Application of mathematical calculus: T= GC + GT+ CT - LCWhere: T: Overlap GC: Hook body GT: End place 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	I. 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			Engargolado Maintenance Personnel	Stop the process line and make the adjustments to the seamer according to procedure MT-PEN-02. Visual inspection and calculation of overlaps after the adjustments are made. S-separate the product from the last effective revision until the moment of detection.	Record review	Seams visual inspection register MT-PCC-EN02
			Continuous process $\label{eq:whole tomatillo 6/10:}$ $210.2 ^{\circ} F \pm 1.8 ^{\circ} F \ \text{per 8 min}$	Temperature and time	Temperature control with a calibrated thermometer and a temperature chart Insert a closed container and time the time from the beginning to the end of the process	At the beginning Each 15 minutes	Continuous sterilizator operator	For temperature deviation below specification: 1. Purge the equipment, so that it recovers temperature (FERLO cookers). 2. Notify quality and the supervisor on duty. 3. Identify the quantity of product affected and segregate it.		Thermal process in continuous lines register PREL/6
Commercial Sterilization	В	Survival of microorganisms; Bacillus cereus, spores of Bacillus coagulans and Clostridium pasterianum.	Batch process Whole tomatillo 6/10: 225 'F -228 'F per 6 min Sauces 6/10: 225 'F -228 'F per 35 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	Retort operator	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



ALLERGEN APPLIED PREVENTIVE CONTROLS PROGRAM

Ingredient Allergen Identification

					Food A	llergens	in Ingr	edients				
Raw material	Manufacturer	Egg	Milk	Soy	Wheat	Tree Nut	Peanut	Fish	Shelfish	Sesame	Sulphites	Preventive Control
Green tomatillo	Guillermo Gómez	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Green tomatillo	Efraín García	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Green tomatillo	Antonio Pimentel	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Green tomatillo	Benito Gómez	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Jalapeño Pepper	Guillermo Gómez	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Jalapeño Pepper	Roberto Gómez	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Jalapeño Pepper	Alfredo Gómez	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Jalapeño Pepper	Ignacio Oloarte	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Jalapeño Pepper	Antonio Pimentel	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)
Coriander	Fernando Cayetano / Carlos Cayetano	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)
Garlic	La Grandeza de León	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Citric acid	RZBC Juxian CO. LTD	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Citric acid	Weifang Ensign Industry CO. LTD	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Xanthan gum	Shandong Fufeng Fermentation CO. LTD	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)
Calcium Chloride	Pochteca Materias Primas, S.A. de C.V.	No	No	No	No	No	No	No	No	No	No	Letter of Guarantee (No Allergens)

Formulation Allergen Identification

					Food Al	lergens	in Forn	nulatior	า			
Formulation	Area	Egg	Milk	Soy	Wheat	Tree Nut	Peanut	Fish	Shelfish	Sesame	Sulphites	Preventive Control
TV	Salt room	No	No	No	No	No	No	No	No	No	No	None
TV	Kitchen room	No	No	No	No	No	No	No	No	No	No	None

Production line and brine preparation area Allergen Identification

				Fo	od aller	gens pr	esent i	n the ar	-ea			
Production Line	Are allergens used in surrounding areas?	Egg	Milk	Soy	Wheat	Tree Nut	Peanut	Fish	Shelfish	Sesame	Sulphites	Preventive Control
6/10 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
Selection area	No	No	No	No	No	No	No	No	No	No	No	None
Salt room	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
	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
Does the product formulation have an intrinsic property that would kill the environmental pathogen of concern?	Yes	Whole green tomatillo, Green mexican sauce and Crushed tomatillo are naturally acid products 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 the cleaning	PRLI/8-4, PRLI/8-5 Cleaning record Lines, ACVL/01 Cleaning Validation Format, PRLI-42 Verification of concentration of cleaning solutions and sanitizers	food contact surfaces with an

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SUPPLY CHAIN APPLIED PREVENTIVE CONTROLS PROGRAM

	PREVENTIVE CONTROLS (PC)									
Ingredient	Ingredient Hazard Critical Limits Monitoring Corrective Action						Corrective Action	Verification	Records	
ingredient		nazaid	Citical Lillins	What	How	Frecuency	Who	COFFECTIVE ACTION	Yermication	necords
Green tomatillo	В	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
Green tomatillo	с	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
Green tomatillo	С	Presence of Pesticides residues above legal limits	According to eCFR Title 40: Protection of Environment PART 180, considering the following groups: Tomatillo, 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
Jalapeño pepper	В	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
Jalapeño pepper	С	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
Jalapeño pepper	С	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	В	Presence of pathogenic bacteria	Absence	Pathogenic bacteria	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	С	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	С	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
Coriander	В	Presence of pathogenic bacteria	Absence	Pathogenic bacteria	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
Coriander	С	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
Coriander	С	Presence of Pesticides residues above legal limits	According to eCFR Title 40: Protection of Environment PART 180, considering the following groups: Clantro, fresh leaves, Coriander, Grop Group 4-16: Leafy Vegetable Group, Crop Group 19: Herbs and Spices Group, Crop Group 25: Herb Group, Crop Group 26: Spice Group	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	С	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



SUPPLY CHAIN APPLIED PREVENTIVE CONTROLS PROGRAM

	PREVENTIVE CONTROLS (PC)								
Ingredient	Ingredient Hazard Critical Limits				toring		Corrective Action	Verification	Records
5			What	How	Frecuency	Who			
Garlic	B Presence of pathogenic bacteria	Absence	Salmonella, O157:H7	Sending of ingredients 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
Gartic	C Mycotoxin growth	12% Humidity max Ref.: Processed Spices and seasonings FAO	% 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
Garlic	C Presence of heavy metals above legal limits	Lead: 0.3 mg/kg Cadmium: 0.2 mg/kg Ref.: CODEX STAN 193-1995	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
Gartic	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	Calculation of concentrations of pesticide residues in the finished product, if they exceed the permissible limits 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
Citric acid	C Presence of heavy metals above legal limits	Not more than 0.5 mg/kg Ref: FAO JECFA Monographs, INS No. 330	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
Xanthan gum	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	Calculation of concentrations of pesticide residues in the finished product, if they exceed the permissible limits 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
Calcium Chloride	C Presence of heavy metals above legal limits	Mg: Not more than 5% F: Not more than 40 mg/kg Pb: Not more than 2 mg/kg Ref.: FAO JECFA INS No. 509	Magnesium, Fluoride, 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
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

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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/6 Thermal process in continuous lines 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, PREL-51 Mexican Sauce Record.
- 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/8-5, 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.

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ANNEX

RISK ASSESSMENT MATRIX

	Probability of occurrences	Impact					
	Probability of occurrences		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, ig 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.

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