

FOOD SAFETY PLAN: CANNED JALAPEÑO 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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Empacadora del Golfo de México, S.A. de C.V. 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	Code:	AC-SGC-FSP-1
	Issue:	11/10/2021
	Revision:	29/11/2022
	Edition:	2

FOOD SAFETY PLAN: CANNED JALAPEÑO PEPPERS



PRODUCT DESCRIPTION

Products Names	Green Nacho Sliced Jalapeño Peppers, Red Nacho Sliced Jalapeño Peppers, Whole Jalapeño Peppers, Seedless Jalapeño Halves, Diced Jalapeño Peppers, Chopped Jalapeño Peppers.
Products Descriptions, including important food safety characteristic	<p>Green / Red Nacho Sliced Jalapeño Peppers: It refers to green or red jalapeño peppers, healthy, ripe and clean, cut transversely into slices nachos 1/4" to 5/16 "thick, firm texture and crunchy.</p> <p>Whole Jalapeño Peppers: It refers to green jalapeño peppers, healthy, ripe and clean with firm and crunchy texture. For whole Jalapeños No. 1 the average weight of chilies is 22 to 30 g and each can must carry a total of 60 to 75 pieces, for Jalapeño No. 2 the average weight is 11-21 g and each can must carry a total of 75-95 pieces.</p> <p>Seedless Jalapeño Halves: It refers to green jalapeño peppers, healthy, ripe and clean, cut in halves free of vein and seeds of firm texture and crunchy.</p> <p>Diced Jalapeño Peppers: It refers to green jalapeño peppers, healthy, ripe and clean, free of tails, subjected to a cut in cubes of (1/4 ").</p> <p>Chopped Jalapeño Peppers: It refers to green jalapeño peppers, healthy, ripe and clean, free of tails, subjected to a transversal cut and later processed in mills.</p> <p>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 3.8 or less, with water activity (aw) greater than 0.85.</p>
Ingredients	Chopped: Jalapeño Peppers, Water, Salt, Acetic Acid. Nacho Sliced, Whole, Seedless & Diced: Jalapeño Peppers, Water, Salt, Acetic Acid, Calcium Chloride.
Type of Packaging	Hermetic packaging (tin steel cans 603x700, 401x411, 303x304x307)
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 ° C, maximum 40 ° C in a clean and dry place.

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**EMPACADORA
DEL GOLFO
DE MÉXICO**

General process step

Process step for seedless only

Process step only for slices, chopped and diced



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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
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.
Salt (granules)	Industria Salinera de Yucatán (Comercial Salinera Roche, S.A. de C.V.)	Mexico	Received in 110 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.
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.
Manual selection, cutting and seed removal	In this stage the jalapeño cut is made in halves and after the deveining (elimination of seed and vein of the pepper).

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Blower	Blowing is carried out for the removal of foreign matter from the raw material.
Washing	The jalapeños are spray washed with chlorinated water (0.2 - 1.5 ppm).
Cut	At this stage the jalapeño pepper is cut into 1/4" or 5/16" thick slices or diced. The percentage of defects must be according to the specification of each product.
Chopped	In this stage the jalapeño is ground with a 3/8 "sieve.
Scalded	Blanching is carried out in a blancher with hot water and steam (T = 149°F - 194°F according to the product), 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 =158°F - 185°F according to the product.
Filled (scalded product and liquid coverage)	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.
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°-194°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. Nacho Sliced 6/10, Whole 6/10, Seedless 6/10 & Diced 6/10: Heating: 208.4° ± 1.8°F per 5 min in continuous sterilization. Heating: 225°F to 228°F per 6 min in batch sterilization. Chopped Jalapeño: Heating: 225°F to 228°F per 45 min in batch sterilization. Nacho Sliced 12/28: Heating: 225°F to 228°F per 6 min in batch sterilization. Nacho Sliced 24/12: Heating: 225°F to 228°F per 5 min in batch sterilization. Heating: 203°F per 6.5 min in continuous 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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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			
Jalapeño Pepper	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. <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. <i>Reference: FSPCA.</i> 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>	1. Supply chain: Supplier development. 2. Process Control (washing of the vegetable with chlorinated water, cooking, acidification of the product). 3. CCP2: Commercial sterilization.
Jalapeño Pepper	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. <i>Reference: WHO.</i> 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. <i>Reference: RASFF Database.</i>	1. Supply chain: Supplier development 2. Verification of raw material by accredited laboratory analysis
Jalapeño Pepper	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. <i>Reference: Health consequences of pesticide use in agriculture, WHO 1992.</i> 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. <i>Reference: Red List FDA, RASFF Database.</i>	1. Supply chain: Supplier development 2. Verification of raw material by accredited laboratory analysis
Jalapeño Pepper	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. <i>Reference: FSPCA.</i> 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
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. <i>Reference: WHO.</i> 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. <i>Reference: RASFF Database.</i>	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). <i>Reference: RASFF Database.</i>	1. Supply chain: Supplier development
Acetic acid	B	No significant food safety risk requiring preventive control is detected.						

HAZARD ANALYSIS (INGREDIENTS AND PACKING MATERIAL)

Ingredient, packing material	Identify <u>potential</u> 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			
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. <i>Reference: WHO.</i> 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. <i>Reference: FAO JECFA Monographs, INS No. 260.</i>	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. <i>Reference: FSPCA.</i> 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. <i>Reference: RASFF Database.</i>	1. Supply chain: Supplier development 2. Verification of concentration before the reception 3. Verification of ingredient by accredited laboratory analysis according to program
Calcium Chloride	B	No significant food safety risk requiring preventive control is detected.						
Calcium Chloride	C	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. <i>Reference: WHO.</i> 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. <i>Reference: FAO JECFA Monographs, INS No. 509.</i>	1. Supply chain: Supplier development 2. Verification of ingredient by accredited laboratory analysis
Calcium Chloride	C	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. <i>Reference: WHO.</i> 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. <i>Reference: RASFF Database</i>	1. Supply chain: Supplier development
Calcium Chloride	P	No significant food safety risk requiring preventive control is detected.						
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. <i>Reference: WHO.</i> 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. <i>Reference: Center for Disease Control and Prevention.</i>	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. <i>Reference: WHO.</i> 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. <i>Reference: EPA.</i> 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



HAZARD ANALYSIS (INGREDIENTS AND PACKING MATERIAL)

Ingredient, packing material		Identify <u>potential</u> 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			
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. <i>Reference: FAO.</i> Seldom: According to the food safety risk databases no recurrent food safety failures due to chemical migration in tinplate containers have been reported. <i>Reference: RASFF Database.</i>	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.						

HAZARD ANALYSIS (PROCESSING STEP)	
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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.						
Manual selection, cutting and seed removal	B	No significant food safety risk requiring preventive control is detected.						
Manual selection, cutting and seed removal	C	No significant food safety risk requiring preventive control is detected.						
Manual selection, cutting and seed removal	P	Contamination with foreign materia: pieces of metal for breaking knives	Critical	Improbable	Medium Low	No	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. Improbable: Is improbable that contamination occurs because it is a manual process is very easy to detect a knife break, there are controls to prevent this from happening.	1. Knives inventories 2. Replacement of knives in case of wear 3. Metal Separation Equipment
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.						
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.						
Cut	B	No significant food safety risk requiring preventive control is detected.						
Cut	C	No significant food safety risk requiring preventive control is detected.						
Cut	P	Contamination with foreign materia: pieces of metal by blades	Critical	Occasional	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.	1. Blade check three times per shift 2. Maintenance check list 3. Magnetic separator
Chopped	B	No significant food safety risk requiring preventive control is detected.						
Chopped	C	No significant food safety risk requiring preventive control is detected.						
Chopped	P	No significant food safety risk requiring preventive control is detected.						

HAZARD ANALYSIS (PROCESSING STEP)	
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HAZARD ANALYSIS (PROCESSING STEP)	
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HAZARD ANALYSIS (PROCESSING STEP)

Processing Step	Identify <u>potential</u> 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			
Commercial sterilization	B	Survival of pathogenic bacterias ; <i>Bacillus cereus</i> , spores of <i>Bacillus coagulans</i> and <i>Clostridium pasteurianum</i> .	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.						

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)									
Processing Step	Hazard		Critical Limits	Monitoring			Corrective Action	Verification	Records
				What	How	Frecuency	Who		
Cut	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	Maintenance staff 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.	Report breakage of glass, fragile or hard plastic, metal and other materials ACPV / 01 PREL/12-RO-JIR Report of raw materials in slicers
Scalded	B	Survival of pathogenic bacteria ; Salmonella, ECEH, Listeria Monocytogenes, Clostridium Botulinum, Bacillus cereu	Whole & Green Nacho Sliced 6/10, 12/28: <u>167° F - 176° F</u> Seedless 6/10 & Nacho Sliced 24/12 (batch sterilization processing): <u>149° F - 167° F</u> Diced 6/10: <u>176° F - 194° F</u> Chopped 6/10: <u>185° F - 194° F</u> Nacho Sliced 24/12 (continuous sterilization processing): <u>176° F - 185° F</u> Red Nacho Sliced 6/10: <u>158° F - 167° F</u>	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	1. Open the Blancher's steam valve further to reach the indicated temperature, 2. Verify the initial temperature of the product prior to the thermal process, 3. If the deviation continues, stop the process and seek mechanical maintenance support.	Verification of CP and CCP (products with thermal process ACPV-PCC/1)
Formulation of liquid coverage	B	Survival of pathogenic bacteria ; Salmonella, ECEH, Listeria Monocytogenes, Clostridium Botulinum, Bacillus cereus	Nacho Sliced 6/10, 12/28, 24/12, Whole 6/10, Seedless 6/10 & Diced 6/10: <u>pH: max 3.0, %Ac: 1.9 - 2.2, %Cl: 5.8 - 6.15</u> Chopped 6/10: <u>pH: 3.0 max, %Ac: 11 - 13, %Cl: 24 - 26</u>	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.	Analysis of coverage fluids ACLC / 1
Heating of liquid coverage	B	Survival of pathogenic bacteria ; Salmonella, ECEH, Listeria Monocytogenes, Clostridium Botulinum, Bacillus cereus	Whole 6/10, Nacho Sliced 6/10, 12/28, Seedless 6/10: <u>158° F - 185° F</u> Diced 6/10, Nacho Sliced 24/12, Chopped 6/10: <u>176° F - 185° F</u>	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.	Verification of CP and CCP (products with thermal process ACPV-PCC/1)
Filled (scalded product and liquid coverage)	B	Survival of pathogenic bacteria ; Salmonella, ECEH, Listeria Monocytogenes, Clostridium Botulinum, Bacillus cereus	Nacho Sliced 6/10: D.W: <u>1680 g max</u> Whole 6/10: <u>100 pieces per can max</u> Seedless 6/10: <u>190 pieces per can max</u> Nacho Sliced 12/28: D.W: <u>480 g max</u> Nacho Sliced 24/12: D.W: <u>250 g max</u> Diced 6/10: D.W: <u>1600 g max</u> Chopped 6/10: N.W: <u>2900 g max</u> , 360 mL liquid coverage min	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.	Whole Jalapeño: Control JA2 PREL/30 Nacho, Diced and Seedless: Verification of CP and CCP (products with thermal process ACPV-PCC/1)
Exhauster	B	Survival of pathogenic bacteria ; Salmonella, ECEH	Products 6/10 & 12/28: <u>176° F - 185° F</u> Nacho Sliced 24/12: <u>172.4° F - 179.6° F</u> Chopped 6/10: <u>185° F - 194° F</u>	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	Verification of CP and CCP (products with thermal process ACPV-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.	Verification of CP and CCP (products with thermal process ACPV-PCC/1)



PROCESS APPLIED PREVENTIVE CONTROLS PROGRAM

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

PREVENTIVE CRITICAL CONTROLS (PCC)										
Processing 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" 401x411: 0.035" 303x307x304: 0.035"	Overlap	Application of mathematical calculus: T= GC + GT+ CT - LC Where: 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 pasteurianum.	Continuous process Nacho Sliced, Seedless & Whole 6/10: 208.4° ± 1.8° F per 5 min Nacho Sliced 24/12: 203° F per 6.5 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.	Record review	Thermal process in continuous lines register PREL/6
			Batch process Nacho Sliced, Seedless, Diced, Whole 6/10 & Nacho 12/28: 225° F - 228° F per 6 min Nacho Sliced 24/12: 225° F - 228° F per 5 min Chopped Jalapeño 6/10: 225° F - 228° F per 45 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 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.		Retort thermal process registers PREL/9

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	Shellfish	Sesame	Sulphites	
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)
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)
Calcium Chloride	Industrias del Alcalí, 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	Shellfish	Sesame	Sulphites	
VJAE1	Salt room	No	No	No	No	No	No	No	No	No	No	None
VJAE2	Kitchen room	No	No	No	No	No	No	No	No	No	No	None
JM	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	Shellfish	Sesame	Sulphites	
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
Hybrid Line	No	No	No	No	No	No	No	No	No	No	No	None
380 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
Odenberg 1	No	No	No	No	No	No	No	No	No	No	No	None
Odenberg 2	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
Green Sliced Jalapeño Pepper 6/10, 12/28 & 24/12, Red Sliced Jalapeño Pepper 6/10, Whole Jalapeño Pepper 6/10, Seedless Jalapeño Halves 6/10, Diced Jalapeño Peppers 6/10, Chopped Jalapeño Peppers 6/10	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	Green Sliced Jalapeño Pepper, Red Sliced Jalapeño Pepper, Whole Jalapeño Pepper, Seedless Jalapeño Halves and Diced Jalapeño Peppers 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/8-1, PRLI/8, 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.

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	Issue:	11/10/2021
	Revision:	29/11/2022
	Edition:	2

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	Frequency	Who			
Jalapeño 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
Jalapeño pepper	C	Presence of Heavy metals above legal limits	Lead 0.1 mg/kg Cadmium 0.05 mg/kg Ref.: Codex Alimentarius Commission 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	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
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
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



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/12-RO-JIR Report of raw materials in slicers, Control JA2 PREL/30.
 - 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/8-1, PRLI/8, 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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	Issue:	11/10/2021
	Revision:	29/11/2022
	Edition:	2

FOOD SAFETY PLAN: CANNED JALAPEÑO PEPPERS



ANNEX

RISK ASSESSMENT MATRIX

Probability of occurrences			Impact				
			Catastrophic	Critical	Moderate	Minor	Negligible
Definition	Meaning	Value	(A)	(B)	(C)	(D)	(E)
Frequent	<ul style="list-style-type: none"> Occurs frequently Will be continuously experienced unless action is taken to change events 	5	5A	5B	5C	5D	5E
Likely	<ul style="list-style-type: none"> Occurs less frequently if corrective action is taken Documented through surveillance 	4	4A	4B	4C	4D	4E
Occasional	<ul style="list-style-type: none"> Occurs sporadically Discovered through surveillance 	3	3A	3B	3C	3D	3E
Seldom	<ul style="list-style-type: none"> Unlikely to occur Rarely, if ever, reported 	2	2A	2B	2C	2D	2E
Improbable	<ul style="list-style-type: none"> 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 breach
- Productions delays
- Technical miscommunications
- Security / confidentiality breaches

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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