FOOD SAFETY PLAN
FOR
10% COLD FILL JUICE BEVERAGE

Disclaimer: This food safety plan is intended to be used as a guide. Each facility should review their ingredients and in-process steps to implement preventive controls to ensure food safety as mandated by the FDA Food Safety Modernization Act (FSMA).

Resource: Food Safety Preventive Controls Alliance (FSPCA) – Preventive Controls for Human Food, First Edition - 2016

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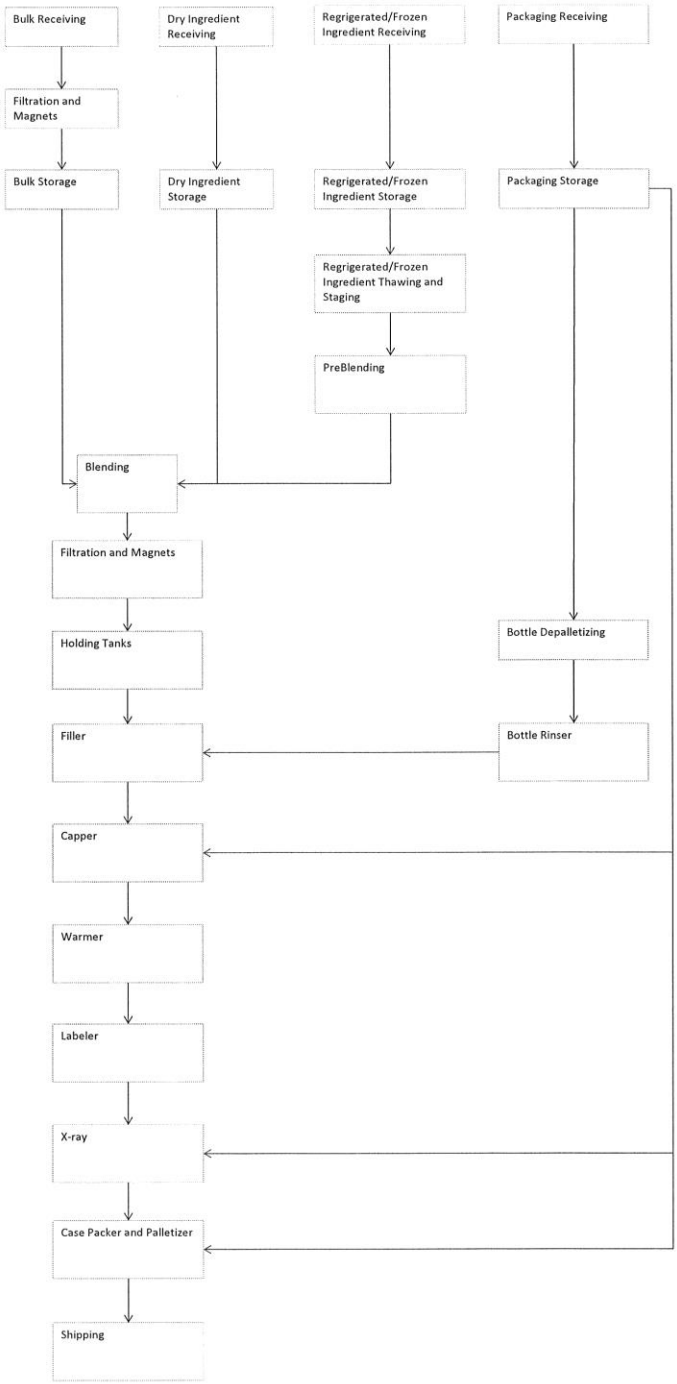
Product Description

Product Name(s)	10% Cold Fill Juice Beverage with Preservatives
Product Description, including Important Food Safety Characteristics	This is a shelf stable cold fill juice beverage packed in a glass bottle. The product is not pasteurized but contains preservatives (sulfites and sodium benzoate). The juice ingredients are processed according to the juice HACCP regulation.
Ingredients	Water, pear juice, pomegranate juice, HFCS, Red 40, natural and artificial flavors, citric acid, ascorbic acid, sodium benzoate and sulfites
pH	~3.2
Packaging Used	Glass
Intended Use	Beverage
Intended Consumers	General public
Shelf Life	9 months
Labeling Instructions	Contains sulfites. Store in cool, dry place. Refrigerate after opening and consume within 10 days after opening.
Storage	Ambient - Pear juice concentrate – frozen - Pomegranate juice concentrate - frozen

Flow Diagram



Process Narrative

Bulk receiving
High fructose corn syrup is received from approved suppliers and placed in bulk storage tanks until use.

Dry ingredient receiving
Citric acid is received in bags and drums. Ascorbic acid (vitamin C) is received in bags or cartons. Sodium benzoate is received in 50 pound bags. Sulfites (e.g., sulfur dioxide, sodium sulfite, sodium bisulfite, potasssium bisulfite, sodium metabisulfite, and potassium metabisulfite) are received in 50 pound bags. FD&C Red 40 is a powder received in bag-in-box packaging.

Refrigerated/frozen ingredient receiving
Pear juice concentrate is received frozen in drums or aseptic in totes or drums. Pomegranate juice concentrate is received frozen in drums. Juice concentrates may also be received refrigerated in bulk tankers.

Liquid ingredient receiving
Natural and artificial flavors are received in pails.

Packaging receiving
Receiving of glass bottles, metal caps, labels and corrugated shippers from suppliers. Packaging materials are stored in a clean dry area.

Filtration and magnets
Bulk ingredients are filtered to remove foreign material and pass through magnets to remove metal objects.

Bulk storage
High fructose corn syrup (HFCS) is stored at ambient temperatures generally between 80°F and 100°F.

Dry ingredient storage
Citric acid and ascorbic are stored in a clean, dry area at ambient temperature. Sodium benzoate should be stored in a cool, dry place in sealed containers. High humidity and elevated temperatures should be avoided for storage. Sulfites should be stored in a cool, dry place. Red 40 is stored at ambient temperature in a dry location. Keep container tightly closed.

Refrigerated/frozen ingredient storage
Refrigerated ingredients are stored at refrigerated temperatures.
Frozen ingredients are stored at the appropriate temperature.

Liquid ingredient storage
Natural and artificial flavors are stored under cool (50°-70°F), dry conditions in tightly sealed containers away from excessive heat and light.

Packaging storage
Packaging materials are stored in a clean, dry area at ambient temperature.

Bottle depalletizing
Bottles are removed from pallets and moved to the production line via a conveyor.

Bottle rinser
Bottles are rinsed with air to remove dust and small loose debris.

Refrigerated/frozen ingredient thawing and staging
Frozen ingredients should be thawed under refrigeration.

Preblending
Pear juice concentrate and pomegranate juice concentrate are blended.

Blending
All ingredients are combined, mixed and held in holding tanks.

Filtration and magnets
After blending, the beverage is passed through filters and magnets to remove any physical contaminants.

Holding Tanks
The juice beverage is transferred to the holding tank prior to the filler.

Filler
The juice beverage is filled cold into glass bottles.

Capper
The metal cap is applied to the bottle at the capper.

Warmer
The filled bottles enter a warming tunnel to warm the containers to ambient temperatures and prevent condensation on the bottles.

Labeler
The filled bottle is labeled appropriately.

X-ray
X-ray technology is used to detect glass in the finished product.

Case packer and palletizer
The finished product is packed in cases and labeled appropriately. The cases are subsequently palletized and stored in a dry place at ambient temperature until shipped to a warehouse or customer.

Hazard Analysis

Hazard identification (column 2) considers those that may be present in the food because the hazard occurs naturally, the hazard may be unintentionally introduced, or the hazard may be intentionally introduced for economic gain.

B = Biological hazards including bacteria, viruses, parasites, and environmental pathogens

C = Chemical hazards including radiological hazards, food allergens, substances, such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives

P = Physical hazards include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects

(1)	(2)	(3)	(4)	(5)	(6)
Ingredient/ processing step	Identify potential hazards introduced, controlled or enhanced at this step (1)	Are any potential food-safety hazards significant? (Yes/No)	Justify your decisions for column 3.	What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?	Is the preventive control applied at this step? (Yes/No)
Packaging Receiving **Glass bottles, metal lids, labels**	Biological - None				
	Glass bottles Physical – Broken glass	Yes	Glass can break and present a hazard if present in the beverage.	Visual inspection and removal of broken glass bottles.	**[No]
Ingredient Receiving **Water**	Biological - None				
	Chemical - None				
	Physical – None	No	No hazards expected when using a potable or municipal water source		
Pear Juice	Biological – pathogens	Yes	Pathogens can be present in untreated juice.	When supplier controls the hazard, supplier verification is triggered (Supply Chain Control). Compliance with Juice HACCP should be considered an appropriate preventive control.	No
	Biological – *C. botulinum*	No	Not a hazard when natural pH is <4.6.		
	Chemical – Inorganic arsenic	No	Not likely to present a hazard due to history of supplier conformance and low level in the finished 10% juice beverage.		
	Chemical – Lead	No	Based on data from suppliers, lead is generally not HRPC given its low		

			probability that the 50 ppb level will be exceeded.		
	Chemical – Pesticide residues	No	Data show low incident of presence of pesticide levels in excess of tolerance and in instances when a tolerance is established, the low levels found do not present a health or safety issue.		
	Physical	Yes	Hard or sharp objects have the potential to be present.	Controlled by the manufacturer of the juice beverage through screens and magnets.	No
Pomegranate Juice	Biological – pathogens	Yes	Pathogens can be present in untreated juice.	When supplier controls the hazard supplier verification is triggered (Supply Chain Control).	No
	Biological – *C. botulinum*	No	Not a hazard when natural pH is <4.6.		
	Chemical – Inorganic arsenic	No	Low probability that pomegranate juice will contain inorganic arsenic at levels of concern. Where the FDA has not developed a level, the Agency will evaluate each juice on a case-by-case basis.		No
	Chemical – Lead	No	Based on data from suppliers, lead is generally not HRPC given its low probability that the 50 ppb level will be exceeded.		
	Chemical – Pesticide residues	No	Data show low incident of presence of pesticide levels in excess of tolerance and in instances when a tolerance is established, the low levels found do not present a health or safety issue.		

	Physical	Yes	Hard or sharp objects have the potential to be present.	Controlled by the manufacturer of the juice beverage through screens and magnets.	No
HFCS	Biological – None				
	Chemical – None				
	Physical – hard or sharp objects could be HRPC	Yes	Hard or sharp objects have the potential to be present.	Controlled by the manufacturer of the juice beverage. Screens and magnets are used later in the process to control foreign objects.	No
Natural and Artificial Flavors	Biological - None				
	Chemical - None				
	Physical – None				
Citric Acid	Biological – None				
	Chemical – None				
	Physical – None				
Ascorbic Acid	Biological – None				
	Chemical – None				
	Physical – None				
Sodium Benzoate	Biological - None				
	Chemical - None				
	Physical - None				
Sulfites	Biological – None				
	Chemical	Yes	Certain consumers have sensitivity to sulfites and the reaction can be severe depending on the level in the product.	In FDA's Juice HACCP guidance, the Agency recommends that controls be implemented for sulfites in concentrations of 10 ppm or more. Control of sulfites in product labeling occurs at the labeler.	No
	Physical - None				
Storage	Biological – None				
	Chemical – None				
	Physical - None				

Blending	Biological – None	No	Environmental pathogens not likely due to GMP and sanitation.		
	Chemical – None	No	Ensure no sanitizer is in the tank prior to blending.		
	Physical – None	No	Controlled by GMPs and screens later in the process.		
Bottle Rinser	Biological – None				
	Chemical – None				
	Physical – Glass fragments	Yes	Broken glass in the bottle would present a potential hazard.	Depending on the manufacturing line, this may be a PC. For example, monitoring of the bottle rinser pressure could be a preventive control to make certain the rinse water is on and of adequate force to effectively remove hazardous fragments. Alternatively, a company may have an optical scanner after the rinser to detect broken glass in the bottle. Each company must have appropriate preventive controls to address glass breakage including a glass break procedure.	**
Filler	Biological – None	No	GMPs and sanitation address any concerns with environmental pathogens.		
	Chemical – None				
	Physical – Glass fragments	Yes	Broken glass in the bottle would present a potential hazard.	Visual monitoring of glass breakage Each company must have appropriate preventive controls to address glass breakage including a glass break procedure. The PC may or may not be applied here.	**

Capper	Biological – None	No	Unlikely introduction of environmental pathogens. GMPs and sanitation address any concerns with environmental pathogens.		
	Chemical – None	No			
	Physical – Glass fragments	Yes	Broken glass in the bottle would present a potential hazard.	This may or may not be a PC depending on the company's process. Visual monitoring of glass breakage Each company must have appropriate preventive controls to address glass breakage including a glass break procedure.	**
Warmer	Biological – None				
	Chemical – None				
	Physical – None				
Labeler	Biological – None				
	Chemical	Yes	Undeclared sulfites would present a hazard.	Operator must check label information and specifically verify the presence of the sulfite ingredient wording.	Yes
	Physical – None				
X-Ray	Biological – None				
	Chemical – None				
	Physical – Glass fragments	Yes	Broken glass in the product presents a safety issue.	X-ray equipment to detect glass in the finished product or any sharp object	**Yes
Case Packing/ Palletizer	Biological – None				
	Chemical – None				
	Physical – None				

**** For each step related to glass, each facility should determine where in the process the preventive control should be applied. This model plan assumes the facility is equipped with x-ray equipment capable of detecting hazardous glass fragments. In the absence of x-ray equipment, the facility should determine where appropriate control should be applied.**

Process Preventive Controls

Process Control(s)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification Activities	Records
			What	How	Frequency	Who			
Labeler	Undeclared sulfites on product labels	Sulfite declaration on the label if contained in the product at a level of 10 ppm or greater	Ensure sulfites are listed in the ingredient statement on the product label	Visual inspection of the label to ensure sulfites are declared in the ingredient statement	Each batch of labels.	Label operator	Reject labels if sulfites are not declared	For each roll or box, label operator verifies that sulfites are included in the ingredient statement for each roll	Label review form.
X-ray	Glass and other foreign material	Equipment is functioning	The integrity of the x-ray equipment	Visual	Daily or at defined frequency	Production employee	Segregate product and rework or destroy. AND Have maintenance personnel check the function of the equipment.	Calibrate x-ray to ensure foreign matter does not enter finished product. Review monitoring, corrective action and verification records at defined frequency.	X-ray integrity log X-ray calibration log

Supply-chain Preventive Controls Program

Determination of Verification Procedures – Audits

Verification activities: A 3rd party supplier audit by a qualified auditor is used to verify supply-chain control of the hazards listed in the table below. Additional verification activities may be conducted as identified in the table below.

Verification procedures: A copy of a 3rd party audit is requested from each supplier listed below on an annual basis. The audit date, auditory qualifications, audit procedures and audit results are reviewed. Follow up discussion with the supplier takes place, as necessary, to verify that any corrective actions mentioned in a report have been completed, with records maintained for this activity.

Records: A copy of audit reports and verification of corrective actions taken by the supplier are maintained on file by the Food Safety Team Leader.

Other Verification Procedures

Raw Material/ Ingredient	**Hazard(s) Requiring a Supply-Chain-Applied Control**	**Preventive Control Applied by Supplier**	**Verification Activities**	**Verification Procedures**	**Acceptance Criteria**
Pear Juice Concentrate	Vegetative pathogens such as *Salmonella*	The supplier complies with Juice HACCP	3rd party audit	See above	See above
Pomegranate Juice Concentrate	Vegetative pathogens such as *Salmonella*	The supplier complies with Juice HACCP	3rd party audit	See above	See above

Approved Suppliers for Ingredients Requiring a Supply-chain-applied Control

Ingredient	**Approved Supplier**	**Date of Approval**	**Hazard(s) requiring supply-chain-applied control**	**Verification Method**	**Verification Record**
Pear Juice Concentrate	Juice R US Happy Town USA	Insert	Vegetative pathogens such as Salmonella	Copy of 3rd party audit documenting compliance with juice HACCP	Copy of audit kept in supplier verification file
Pomegranate Juice Concentrate	Juice R US Happy Town USA	Insert	Vegetative pathogens such as Salmonella	Copy of 3rd party audit documenting compliance with juice HACCP	Copy of audit kept in supplier verification file

Receiving Procedures: For each shipment received, the receiving clerk uses the receiving database to identify required documentation then:

- verifies that the product is from an approved supplier
- verifies that each lot in the shipment is accompanies by a COA, if appropriate
- reviews each COA against acceptance criteria above, as appropriate, and
- documents the above in the Incoming Goods Log.

Allergen Preventive Controls

Allergen Controls	Hazard(s)	Criteria	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			

Allergen Label Verification Listing	
Products	**Allergen Statement**
	Contains:
	Contains:

Alternate Format – Food Allergen Ingredient Analysis

The format below is an alternative for an allergen specific hazard analysis. If you choose to use a form like this, then there is no need to duplicate allergen considerations in your hazard analysis chart. Duplication of information in multiple forms can create extra work and may lead to inconsistencies. Some organizations may even choose to do an ingredient hazard analysis that considers not only allergens, but also other hazards. This may be a useful option for you.

How to Use the Chart
List all ingredients received in the facility. Identify allergens contained in each ingredient by reviewing ingredient labels or contacting the manufacturer. Any allergens listed in "May contain" or other precautionary labeling on ingredients should be listed in the last column and reviewed to determine if allergen labeling is needed on the finished product.

		Food Allergens in Ingredient Formulation								
Raw Material Name	**Supplier**	**Egg**	**Milk**	**Soy**	**Wheat**	**Tree Nut (market name)**	**Peanut**	**Fish (market name)**	**Shellfish (market name)**	**Allergens in Precautionary Labeling**

Production Line Allergen Assessment

Complete for each production line. Identify each allergen contained in each product produced on the line. Identify any allergens unique to a specific product, then indicate scheduling information (i.e., run unique allergens last) and allergen cleaning information (i.e., full allergen clean before running cheese or plain omelets after a biscuit run).

		Intentional Allergens							
Product Name	**Production Line**	**Egg**	**Milk**	**Soy**	**Wheat**	**Tree Nut (market name)**	**Peanut**	**Fish (market name)**	**Shellfish (market name)**

Scheduling Implications:

Allergen Cleaning Implications:

Sanitation Preventive Controls

Location		
Purpose		
Frequency		
Who		
Procedure		
Monitoring		
Corrections		
Records		
Verification		**Date**