

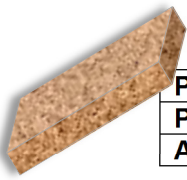
Group 4: Granola Bar



**Contains: rolled oats, honey, and lecithin (pan release)
0.95 oz. single serve**

Packaged 144 per box. Meant for individual sale.

Lab data: pH 6.1, Aw 0.55



PRODUCT(S): Cold Pressed Almond Cranberry Energy Bar	PAGE 1 of 16	
PLANT NAME: Example	ISSUE DATE	01/28/2016
ADDRESS: 123 Xyz Street, USA	SUPERSEDES	10/22/2015

Selected Sections of a

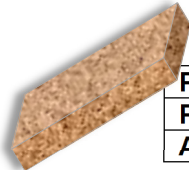
Food Safety Plan
for
Cold Pressed Energy Bar

Teaching Example

Reviewed by: _____ Plant Manager Date: _____

The information in this example is for training purposes only and does not represent any specific operation. Many processing steps were omitted or combined to facilitate its use for class exercises. Thus **it is not complete and contains both required and optional information.** Because development of a Food Safety Plan is site specific, it is highly unlikely that this plan can be used in a specific facility without significant modification. Conditions and specifications used (e.g., validation information) are for illustrative purposes only and may not represent actual process conditions.

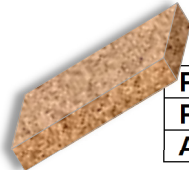
NOTE: This example refers to Standard Operating Procedures (SOP) to illustrate that separate procedures can be used to provide more detail. The details of these SOPs are not included in this teaching example, but would be subject to regulatory review.



PRODUCT(S): Cold Pressed Almond Cranberry Energy Bar	PAGE 2 of 16	
PLANT NAME: Example	ISSUE DATE	01/28/2016
ADDRESS: 123 Xyz Street, USA	SUPERSEDES	10/22/2015

Table of Contents

Company Overview.....	3
Product Description.....	3
Flow Diagram.....	4
Process Narrative	5
Ingredients and Packaging Materials	5
Receive Ingredients.....	5
Receive Packaging.....	5
Store Ingredients	5
Store Packaging	6
Measure Ingredients.....	6
Mix and Warm Syrup.....	6
Cool Syrup.....	6
Mix Dry Ingredients	6
Blend All Ingredients	6
Pan Release Spray	6
Form/Press.....	6
Setting	6
Cutting	6
Rework	6
Metal Detection	6
Wrap, Case	7
Store, Ship.....	7
Hazard Analysis	8
Process Preventive Controls.....	12
Allergen Preventive Controls	13
Ingredient Allergen Identification	13
Production Line Allergen Assessment.....	13
Allergen Label Verification Listing	13
Allergen Preventive Control Chart.....	14
Sanitation Preventive Controls.....	15
Zoning and Related GMP Controls	15
Cleaning and Sanitation	15
Microbiological Verification of Sanitation Practices	15
Supply-chain Preventive Controls Program	16



PRODUCT(S): Cold Pressed Almond Cranberry Energy Bar	PAGE 3 of 16	
PLANT NAME: Example	ISSUE DATE	01/28/2016
ADDRESS: 123 Xyz Street, USA	SUPERSEDES	10/22/2015

Company Overview

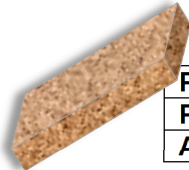
This example company is a small firm that makes a variety of ready-to-eat energy bars. The cold pressed products are manufactured through the preparation of a binding syrup that is combined with a dry ingredient mix. The mass is formed/pressed and allowed to set prior to cutting and packaging in foiled bags. They do not receive any kill step during processing. The following products are produced in the facility using some of the same equipment:

- Almond, Cranberry Bar (**described in this plan**)
- Chocolate Covered Peanut Bar (described in a separate plan)
- Sunflower Seed, Raisin Bar (described in a separate plan)

Product is made 5 days a week in one 8 hour production shift, followed by 4 hours for sanitation. Dry cleaning is used in production areas, with select small pieces of equipment being cleaned in a separate wet washing room. Water is treated and tested per EPA requirements by the city. An integrated pest control program is also in place.

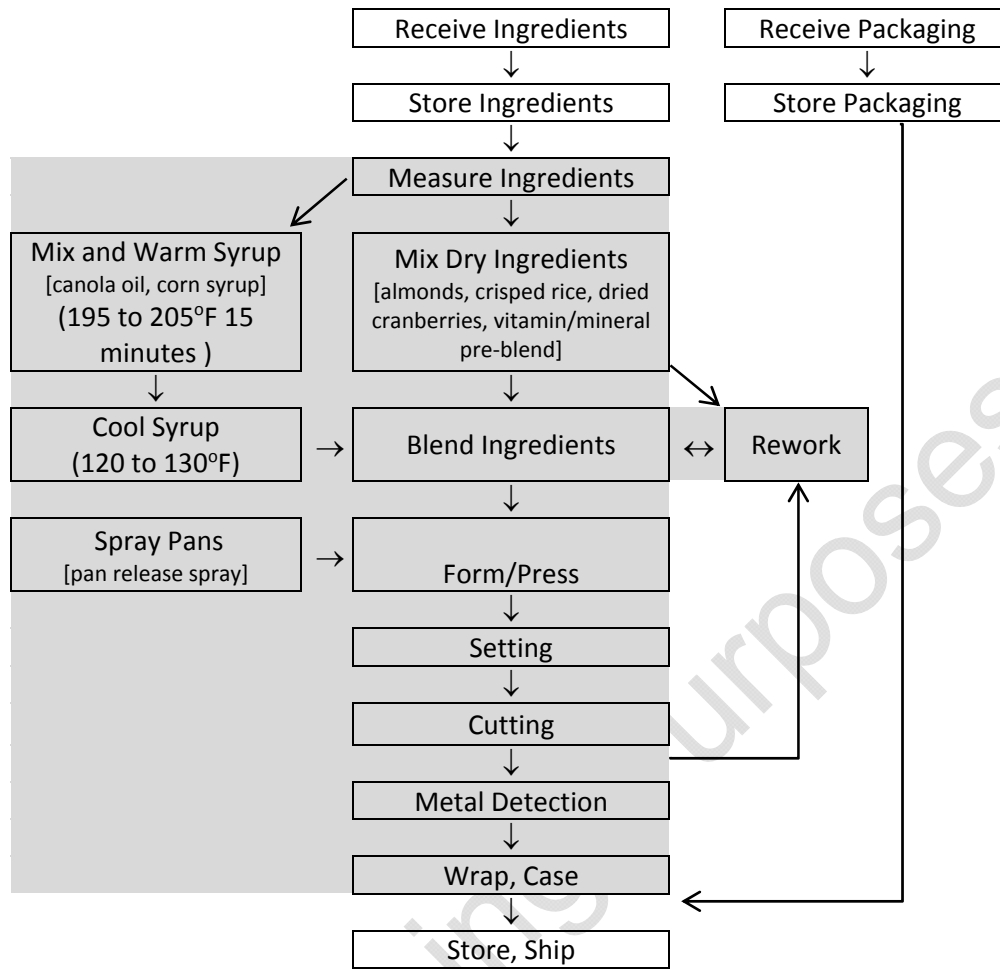
Product Description

Product Name(s)	Almond, Cranberry Energy Bar	
Product Description, including Important Food Safety Characteristics	This product is a ready to eat energy bar packed in a pouch for on-the-go eating. The low water activity makes the product shelf stable. Processing involves dry mixing and forming with no process lethality step. Water activity ≤ 0.65	
Ingredients	Corn syrup, blanched/slivered almonds, crisped rice, dried cranberries, canola oil, pan release agent (soy lecithin), vitamin and mineral pre-blend	
Packaging Used	Metalized polyethylene film, individual retail package with label	
Intended Use	Ready-to-eat bars	
Intended Consumers	General consumption	
Shelf Life	One year	
Labeling Instructions	None	
Storage and Distribution	Ambient, not to exceed 90°F	
Approved: Signature: <i>F.S. Leader</i> Print name: F.S. Leader	Date: 05 January 2016	



PRODUCT(S): Cold Pressed Almond Cranberry Energy Bar	PAGE 4 of 16	
PLANT NAME: Example	ISSUE DATE	01/28/2016
ADDRESS: 123 Xyz Street, USA	SUPERSEDES	10/22/2015

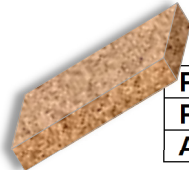
Flow Diagram



Gray area indicates primary pathogen control area

Verified by: *P. I. Model*

Date: January 5, 2016



PRODUCT(S): Cold Pressed Almond Cranberry Energy Bar	PAGE 5 of 16	
PLANT NAME: Example	ISSUE DATE	01/28/2016
ADDRESS: 123 Xyz Street, USA	SUPERSEDES	10/22/2015

Process Narrative

Ingredients and Packaging Materials

Ingredients and packaging materials are purchased from approved suppliers that comply with internationally recognized food safety and quality systems. Suppliers that provide ingredients and raw materials that have a history of the presence of significant hazards for which we do not have an effective control in our facility are evaluated through an on-site audit (trusted third party audit) and are included in a supplier verification program. For each ingredient, the same brand is used consistently to minimize variation. Ingredients are stored according to manufacturers' recommendations when specified.

Receive Ingredients

Corn syrup – Received in 5 gallon plastic containers

Canola oil – Received in 5 gallon plastic containers

Almonds, blanched and slivered – Received in 20 lb. bags. Specifications require blanching after shelling and sorting for defects and mold. Prior to blanching, shelled almonds are treated with propylene oxide (PPO) to achieve the minimum 4-log reduction of *Salmonella* required for California almonds in North America. Screening and testing for aflatoxin is also conducted. Quarterly, Certificates of Analysis (COA) for *Salmonella*, Enterobacteriaceae and aflatoxin conformance to specifications accompany shipments.

Crisped rice – Received in 22 lb. bag-in-box. Ingredients include rice flour, corn flour, sugar and salt.

Dried cranberries – Received in 25 lb. cases. Ingredients include cranberries, sugar and sunflower oil. Packaged in the same facility as peanuts, tree nuts, soy, and milk products.

Vitamin/ mineral pre-blend – Vitamins (A, B-mix, C, E) and minerals (Ca, Mg, K, Zn) received in 1 lb. plastic sealed bags, with 10 bags in a box. Certificates of analysis accompany each shipment, confirming levels of vitamins and minerals.

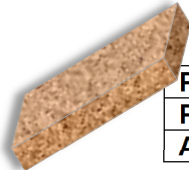
Pan release agent – contains soy lecithin – received in spray cans

Receive Packaging

Corrugated shippers and pre-printed metalized film are received in bulk at the factory. Specifications require food grade material for metalized film. Suppliers provide a Certificate of Conformance that packaging materials and inks meet food safety and regulatory requirements. Appropriate allergen label information is included in the specification and reviews are conducted for each receipt, including listing almonds and soy lecithin on the ingredient statement, followed by “Contains Almond, Soy” and “May Contain” peanuts, tree nuts and milk on the precautionary statement.

Store Ingredients

All ingredients are stored in the dry storage room (temperature kept below 75°F) in the ingredient area, arranged by ingredient code number. All containers are sealed to avoid cross-contact and cross-contamination during storage. Ingredients that contain allergens are labelled and stored in specific locations with like allergenic ingredients.



PRODUCT(S): Cold Pressed Almond Cranberry Energy Bar	PAGE 6 of 16	
PLANT NAME: Example	ISSUE DATE	01/28/2016
ADDRESS: 123 Xyz Street, USA	SUPERSEDES	10/22/2015

Store Packaging

Cartons and trays are stored in the dry storage room adjacent to the packaging area. Unused trays are covered during storage between uses. Plastic wrap is stored in sealed containers to protect from contamination. Packaging is used First-In-First-Out.

Measure Ingredients

Ingredients are measured and staged in a dedicated room. The hygiene level of the room is consistent with the requirements of exposed product manufacturing areas. Allergenic materials are weighed on dedicated equipment into dedicated containers using color coded tools dedicated to the allergen. Employees change smocks and gloves before and after handling an allergenic material.

Mix and Warm Syrup

Corn syrup and canola oil are added to a jacketed mixer and warmed to 195 to 205°F and blended for 20 minutes to ensure even distribution. Warming facilitates more uniform blending and is not intended to be a kill step in these low water activity ingredients.

Cool Syrup

The syrup is cooled to 120-130°F and held in the mixer until needed.

Mix Dry Ingredients

Almonds, crisped rice, dried cranberries, and the vitamin/mineral pre-blend are added to a mixer and blended for 30 minutes to ensure even distribution.

Blend All Ingredients

Mixed dry ingredients are gradually added to the syrup mixer. Rework is added at this step.

Spray Pans

Pans that have been cleaned and dried are sprayed by hand with a processing aid containing soy lecithin.

Form/Press

The blended mass is dispensed onto pans. The mixture is formed and pressed with rollers to ensure consistent spreading and density.

Setting

Pans are moved to setting area where they are cooled to ambient temperature around 70°F.

Cutting

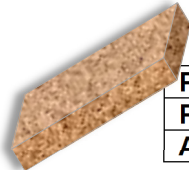
Sheets are cut mechanically in two successive cutting operations, vertically and horizontally (rotary blade, reciprocal blade).

Rework

Rework may be generated from the mixing operation, blending operation or after cutting of sheets. Rework is collected in clean and dry containers, which are labelled with the product name, relevant allergens, and date rework was generated. Allowable rework use is calculated based upon the composition of the rework. Rework is used according to a rework/allergen matrix to ensure that no undeclared allergens are introduced into products. Potential rework material is discarded approximately monthly to break the rework "chain," which simplifies traceability.

Metal Detection

Cut bars are passed through a calibrated metal detector on the conveyor. Bars that are kicked off during this operation are passed through a more sensitive metal detector. Rejected bars are



PRODUCT(S): Cold Pressed Almond Cranberry Energy Bar	PAGE 7 of 16	
PLANT NAME: Example	ISSUE DATE	01/28/2016
ADDRESS: 123 Xyz Street, USA	SUPERSEDES	10/22/2015

inspected and sent to waste. The performance of the metal detector is verified once an hour using metal detectable wands containing 1.5 mm ferrous and 2.0 mm stainless steel.

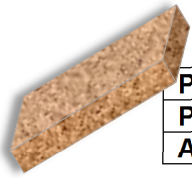
Wrap, Case

The identity of wrapping material is confirmed for each batch placed on the line to ensure that it is the correct material and contains relevant allergen declaration information. Trays containing cut bars are flipped onto wrappers and bars are individually heat sealed and cut. Lot information is printed onto each sealed package. Bars are transferred by hand into cases, with 24 bars/case. Product and lot information is printed on each case. Cases are transferred by hand to pallets, which are sealed in plastic.

Store, Ship

Pallets are transferred by fork lift to the warehouse where they are stored under ambient condition at < 70% RH until shipping.

For Training Purposes Only



PRODUCT(S): Cold Pressed Almond Cranberry Energy Bar	PAGE 8 of 16	
PLANT NAME: Example	ISSUE DATE	01/28/2016
ADDRESS: 123 Xyz Street, USA	SUPERSEDES	10/22/2015

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.

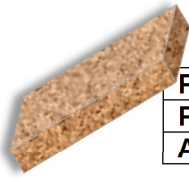
B = Biological hazards including bacteria, viruses, parasites, and environmental pathogens

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) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Are any <u>potential</u> food safety hazards requiring a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Receive Ingredients: Corn syrup, Canola oil	B None						
	C None						
	P None						
Receive Ingredients: Almonds	B <i>Salmonella</i>	X		Untreated almonds have a history of <i>Salmonella</i> issues	Supply-chain control – Approved supplier 3 rd party audit and quarterly testing by supplier		X
	C Aflatoxin	X		Almonds have a history of potential contamination with aflatoxin	Supply-chain control – Quarterly testing by supplier		X
	Undeclared allergen – almond	X		Almonds are tree nuts that are a recognized food allergen	Allergen control – Label review and allergen cross-contact prevention		X
	P Shell pieces		X	Pieces are removed at supplier during sorting, including optical sorter. Consumer complaint data do not indicate an issue			
Receive Ingredients: Crisped rice	B <i>Salmonella</i>	X		A few cereal outbreaks have occurred, but not with this specific type of process. Warrants supplier program at a reduced level of concern.	Supply-chain control – Approved supplier 3 rd party audit		X
	C None						
	P None						
Receive Ingredients: Dried cranberries	B <i>Salmonella</i>		X	Process to manufacture cranberries has sufficient lethality. If present, <i>Salmonella</i> levels will decrease during storage			
	C Allergens	X		Cranberries are not a food allergen, but ingredient has precautionary labeling for other food allergens handled at supplier facility	Allergen control – Subsequent allergen labeling		X
	P None						
Receive Ingredients: Vitamin/ mineral pre- blend	B None						
	C None						
	P None						

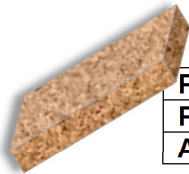
Continued



PRODUCT(S): Cold Pressed Almond Cranberry Energy Bar	PAGE 9 of 16	
PLANT NAME: Example	ISSUE DATE	01/28/2016
ADDRESS: 123 Xyz Street, USA	SUPERSEDES	10/22/2015

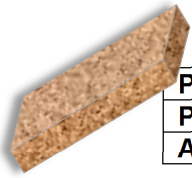
(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Are any <u>potential</u> food safety hazards requiring a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Receive Ingredients: Pan release agent	B None						
	C Undeclared allergen – soy	X		Soy is a recognized food allergen. All products use this processing aid, so cross-contact is not relevant.	Allergen control – Subsequent allergen labeling		X
	P None						
Receive Packaging	B None						
	C Undeclared allergens	X		Printing errors have occurred and a correct allergen statement is essential for safety. Packaging line operators check the label number but not necessarily the allergen information.	Allergen control – Verify allergen labeling	X	
	P None						
Store Ingredients	B None						
	C Undeclared allergens		X	Ingredients with allergens are stored in the warehouse in segregated areas and in sealed containers, easily managed by general controls.			
	P None						
Store Packaging	B None						
	C None						
	P None						
Measure Ingredients	B Environmental pathogens such as <i>Salmonella</i>	X		Cross-contamination possible if measuring environment not managed at appropriate hygiene level.	Sanitation controls - Zoning, dry environment	X	
	C Food allergens from other products	X		Materials containing allergens other than those on the label are handled in the same environment.	Allergen controls – Proper cleaning between allergens. Use of dedicated tools, run order of allergenic materials	X	
	P None						
Mix and Warm Syrup	B Environmental pathogens such as <i>Salmonella</i>		X	Cross-contamination possible if environment and employee practices not managed at appropriate hygiene level.	Sanitation control - Zoning, maintaining dry environment	X	
	C None						
	P None						
Cool Syrup	B Environmental pathogens such as <i>Salmonella</i>		X	Cross-contamination possible if environment and employee practices not managed at appropriate hygiene level.	Sanitation control - Zoning, maintaining dry environment	X	
	C None						
	P None						

Continued



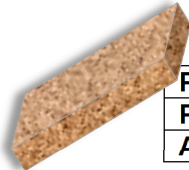
PRODUCT(S): Cold Pressed Almond Cranberry Energy Bar	PAGE 10 of 16	
PLANT NAME: Example	ISSUE DATE	01/28/2016
ADDRESS: 123 Xyz Street, USA	SUPERSEDES	10/22/2015

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Are any <u>potential</u> food safety hazards requiring a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Mix Dry Ingredients	B Environmental pathogens such as <i>Salmonella</i>	X		Cross-contamination possible if environment and employee practices not managed at appropriate hygiene level.	Sanitation controls – Zoning , maintaining dry environment	X	
	C Food allergens from other products	X		Materials containing allergens other than those on the label are handled in the same environment.	Allergen controls – Proper cleaning between allergens. Use of dedicated tools, run order of allergenic materials	X	
	P Metal	X		Metal-on-metal contact occurs in equipment	Subsequent metal detection		X
Blend All Ingredients	B Environmental pathogens such as <i>Salmonella</i>	X		Cross-contamination possible if environment and employee practices not managed at appropriate hygiene level.	Sanitation control - Zoning, maintaining dry environment	X	
	C Food allergens from other products	X		Materials containing allergens other than those on the label are handled in the same environment.	Allergen controls – Proper cleaning between allergens. Use of dedicated tools, run order of allergenic materials	X	
	P Metal	X		Poorly maintained or improperly operated mixer could generate foreign bodies. Preventive maintenance reduces occurrence	Other control – Preventive maintenance	X	
Spray Pans	B Environmental pathogens such as <i>Salmonella</i>	X		Cross-contamination possible if environment and employee practices not managed at appropriate hygiene level.	Sanitation control – Zoning, maintaining dry environment	X	
	C Food allergens from other products	X		Materials containing allergens other than those on the label are handled in the same environment.	Allergen controls – Proper cleaning between allergens. Use of dedicated tools, run order of allergenic materials	X	
	P None						
Form/ Press	B Environmental pathogens such as <i>Salmonella</i>	X		Cross-contamination possible if environment and employee practices not managed	Sanitation control – Zoning, maintaining dry environment	X	
	C Food allergens from other products	X		Materials containing allergens other than those on the label are handled in the same environment.	Allergen controls – Proper cleaning between allergens. Use of dedicated tools, run order of allergenic materials	X	
	P Metal	X		Poorly maintained or improperly use pressing equipment could generate metal fragments. Preventive maintenance reduces occurrence	Subsequent metal detection		X
<i>Continued</i>							



PRODUCT(S): Cold Pressed Almond Cranberry Energy Bar	PAGE 11 of 16	
PLANT NAME: Example	ISSUE DATE	01/28/2016
ADDRESS: 123 Xyz Street, USA	SUPERSEDES	10/22/2015

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Are any <u>potential</u> food safety hazards requiring a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Setting	B Environmental pathogens such as <i>Salmonella</i>	X		Cross-contamination possible if environment and employee practices not managed at appropriate hygiene level.	Sanitation control – Zoning, maintaining dry environment	X	
	C Food allergens from other products	X		Materials containing allergens other than those on the label are handled in the same environment.	Allergen controls – Proper cleaning between allergens. Use of dedicated tools, run order of allergenic materials	X	
	P None						
Cutting	B Environmental pathogens such as <i>Salmonella</i>	X		Cross-contamination possible if environment and employee practices not managed	Sanitation control – Zoning, maintaining dry environment	X	
	C Food allergens from other products	X		Materials containing allergens other than those on the label are handled in the same environment.	Allergen controls – Proper cleaning between allergens. Use of dedicated tools, run order of allergenic materials	X	
	P Metal	X		Poorly maintained or improperly used cutting equipment could generate metal fragments.	Subsequent metal detection		X
Rework	B Environmental pathogens such as <i>Salmonella</i>	X		Cross-contamination possible if processing environment and employee practices not managed at appropriate hygiene level.	Sanitation control – Zoning, maintaining dry environment and equipment, proper drying after allergen changeover	X	
	C Food allergens from other products	X		Materials containing allergens other than those on the label are handled in the same environment.	Allergen controls – Use of dedicated storage containers, rework use matrix run order of allergenic materials, proper cleaning of tools and equipment between allergens, employee GMP	X	
	P None						
Metal Detection	B None						
	C None						
	P Metal inclusion	X		Metal may be present from previous operations	Process control – metal detector	X	
Wrap, Case	B Environmental pathogens such as <i>Salmonella</i>	X		Cross-contamination possible if processing environment and employee practices not managed at appropriate hygiene level.	Sanitation preventive control – Zoning, maintaining dry environment and equipment, proper drying after allergen changeover	X	
	C Undeclared allergens – almond, soy	X		The product contains almonds and soy which are food allergens. The wrapper has the labeling	Allergen Control – verification appropriate label used	X	
	P None						
Store, Ship	B None						
	C None						
	P None						



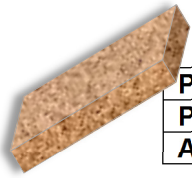
PRODUCT(S): Cold Pressed Almond Cranberry Energy Bar	PAGE 12 of 16	
PLANT NAME: Example	ISSUE DATE	01/28/2016
ADDRESS: 123 Xyz Street, USA	SUPERSEDES	10/22/2015

Process Preventive Controls

Process control(s)	Hazard(s)	Critical limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Metal detection	Metal inclusion								

See the Food Safety Plan in the curriculum for an example of potential wording for metal detection. Parameters can vary depending on the product, packaging, detection system, etc.

For Training Purposes Only



PRODUCT(S): Cold Pressed Almond Cranberry Energy Bar	PAGE 13 of 16	
PLANT NAME: Example	ISSUE DATE	01/28/2016
ADDRESS: 123 Xyz Street, USA	SUPERSEDES	10/22/2015

Allergen Preventive Controls

Ingredient Allergen Identification

Raw Material Name	Supplier	Allergens in Ingredient Formulation								Allergens in Precautionary Labeling
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	
Blanched almonds	BIG Almond Company					Almond				None
Dried cranberries	Fruit & Nut Ltd.									Packed in a facility that also produces peanuts, tree nuts, soy and milk
Corn syrup	G. Narich Sweeteners, Inc.									None
Crisped rice	A. Cereal Company									None
Pan release agent	My Distributor			X						None
Vitamin/ Mineral Pre-blend	CarGen Nutritionals									None

Production Line Allergen Assessment

Product Name	Production Line	Intentional Allergens							
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)
Almond Cranberry Bar	1 and 2			X		Almond			
Chocolate Covered Peanut Bar	1 and 2		X	X			X		
Sunflower Seed Raisin Bar	1			X					

Scheduling Implications:

Standard practice is to run the Sunflower Seed Raisin Bar in the beginning of the shift to reduce the potential for allergen cross-contact.

Allergen Cleaning Implications: (Required)

A full allergen clean is **required** AFTER production of Chocolate Covered Peanut Bar and Almond Cranberry Bar because they contain unique allergens (see table)

Allergen Label Verification Listing

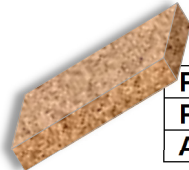
Product	Allergen Statement	Label Number
Almond Cranberry Bar	Contains: Almond, soy Manufactured on equipment that also handles peanuts, other tree nuts, and milk	AC123
Chocolate Covered Peanut Bar	Contains: Peanut, milk, soy Manufactured on equipment that also handles tree nuts	CP456
Sunflower Seed Raisin Bar	Contains: Soy Manufactured in a facility that also handles peanuts, tree nuts and milk	SSR789



PRODUCT(S): Cold Pressed Almond Cranberry Energy Bar	PAGE 14 of 16	
PLANT NAME: Example	ISSUE DATE	01/28/2016
ADDRESS: 123 Xyz Street, USA	SUPERSEDES	10/22/2015

Allergen Preventive Control Chart

Allergen control	Hazard(s)	Criteria	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Receiving packaging (labeled wrapper)	Undeclared allergens – almonds, soy lecithin Precautionary labeling: Manufactured on equipment that also handles peanuts, other tree nuts, and milk	Product label declares allergens present in the formula and has precautionary labeling from ingredients	Ingredient listing and allergen declaration matches product	Visual exam of wrapper label to match product formula per SOP 14-264	Each receipt before release to production	Label specialist	If label is incorrect, reject labels and return to supplier or destroy. Identify root cause and conduct training as needed or discuss with supplier how to prevent recurrence	QA manager or designee reviews and initials records within 7 working days and compares results with past results to identify any trends	Allergen Label Verification Listing Allergen Label Verification at Receipt Log Corrective action records Verification records
Wrap, Case (labeled wrapper)	Undeclared allergens – almonds, soy lecithin and Precautionary labeling	Label number matches product	Confirm that packaging used matches the product number	Visual inspection of the wrapper stock to match the product number	Beginning and end of run and when label stock is changed	Line operator	If label is incorrect, segregate product, inspect back to the last good check, relabel or destroy; identify root cause and conduct training as needed to prevent recurrence		Allergen Label Verification Listing Allergen Label Verification on Line Log Corrective action records Verification records
Allergen change over procedures, including clean following the use of other allergenic material on equipment	Cross-contact with allergens not present in the recipe	No residual allergenic material from previous production	Application of effective cleaning; visual inspection prior to start-up	Procedures as outlined in Allergen Change Over Procedures – SOP 14-456	After products containing allergenic materials not in this recipe are handled on the line	Sanitation manager	Re-clean line	Hygiene audit; ATP swabs	Sanitation log Corrections records Verification records



PRODUCT(S): Cold Pressed Almond Cranberry Energy Bar	PAGE 15 of 16	
PLANT NAME: Example	ISSUE DATE	01/28/2016
ADDRESS: 123 Xyz Street, USA	SUPERSEDES	10/22/2015

Sanitation Preventive Controls

Zoning and Related GMP Controls

The ingredient measurement room and processing areas are maintained at a higher hygiene level than receiving, storage, and shipping areas, as specified in SOP 15-123 – High Hygiene Sanitation Procedures.

As specified in SOP 15-456 – Employee Hygiene in High Hygiene Areas, employees must put on smocks that do not have pockets, change into factory shoes, put on protective equipment (hair net, beard net), and wash their hands before entering ingredient measurement and production areas.

Rework is covered and stored in a room adjacent to the processing area, and maintained at the same hygiene level as the processing area (See SOP 15-789 – Rework Procedures).

Equipment and utensils that are cleaned out-of-place are cleaned and sanitized in a wash room adjacent to the processing areas. Clean equipment is dried and stored on racks in an area adjacent to the processing area. The cleaning and sanitation crew have a dedicated room to store cleaning equipment.

Cleaning and Sanitation

The warehouse and loading areas are dry cleaned. Ingredient measurement room, production areas and rework storage rooms are maintained dry during production. Lines and equipment are wet cleaned and sanitized when changing over from a product containing a different allergen. Equipment is completely dried prior to production. See these Standard Operating Procedures for details:

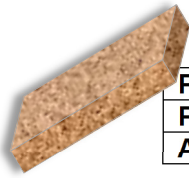
- SOP 16-454 – Dry Cleaning
- SOP 16-455 – Controlled Wet Cleaning
- SOP 14-456 – Allergen Change Over

Microbiological Verification of Sanitation Practices

A *Salmonella* environmental monitoring program is in place to verify that controls are sufficient to prevent the presence and harborage of *Salmonella* in the environment and equipment. The program includes an evaluation of Enterobacteriaceae levels as an additional verification that conditions do not exist that could lead to the presence and harborage of *Salmonella*. Enterobacteriaceae environmental monitoring occurs weekly and *Salmonella* monitoring occurs monthly.

Additional environmental monitoring is conducted in the event of special circumstances, including maintenance in the ingredient measurement room and processing areas; leaks that introduce water into the ingredient measurement room and processing areas (other than normal controlled wet cleaning); or audit findings suggesting sanitation controls may be inadequate. See:

- SOP 15-282: Environmental Monitoring Verification Procedures
- SOP 15-283 Environmental Monitoring for Special Circumstances



PRODUCT(S): Cold Pressed Almond Cranberry Energy Bar	PAGE 16 of 16	
PLANT NAME: Example	ISSUE DATE	01/28/2016
ADDRESS: 123 Xyz Street, USA	SUPERSEDES	10/22/2015

Supply-chain-applied Preventive Controls Program

The following suppliers provide ingredients or raw materials requiring a supply-chain-applied control because we do not have an effective control in our facility. Each of these approved suppliers is evaluated through an on-site third party audit conducted by a qualified auditor. Additional verification activities are also conducted as noted below. The supplier approval process is documented in SOP 16-321.

Raw Material or Ingredient	Almonds		Crisped Rice
Approved Supplier and location	B.I.G. Almond Company, Nuttown, USA		A. Cereal Company, Grainbelt, USA
Approval Date	10/08/2010		9/9/2009
Hazard requiring a Supply-chain-applied Control	<i>Salmonella</i>	Aflatoxin	<i>Salmonella</i>
Preventive Controls Applied by the Supplier	Propylene oxide treatment required for California almonds in North America achieves a minimum 4-log reduction of <i>Salmonella</i>	Sorting to remove moldy nuts that may contain aflatoxin	The crisping process provides sufficient heat to kill <i>Salmonella</i> . Zoning and dry cleaning used to prevent recontamination.
Type(s) of Supplier Verification	3 rd party audit of approved supplier and quarterly certificates of analysis (COA)		3 rd party audit of approved supplier
Verification Procedure(s)	<p>A copy of a 3rd party audit is requested from the supplier annually. The audit date, auditor qualifications, audit procedures and audit results are reviewed by our Quality Assurance Manager. Follow up with the supplier takes place, as necessary, to verify that any corrective actions mentioned in the report have been completed, with records maintained for this activity.</p> <p>For each shipment received, the incoming goods technician verifies that the material is from the approved supplier location using the Bill of Lading, documents the check in the incoming goods log and files the Bill of Lading.</p> <p>Certificates of Analysis The incoming goods technician:</p> <ul style="list-style-type: none"> visually checks the COA for compliance with specification (see below), documents the check in the incoming goods log and files the COA with supplier records. <p>If the COA is not provided in the required timeframe, the lot is put on hold and a COA is requested. The lot is rejected if no COA is provided for the lot.</p>		
	<i>Salmonella</i> not detected in 5 × 25g samples per lot	Aflatoxin < 10 ppm for lots received	NA
Records – ingredient or hazard specific – required for all	Quarterly COAs <i>Salmonella</i>	Quarterly COAs for aflatoxin	See list below
	<ul style="list-style-type: none"> A copy of the audit report and verification of corrective actions taken by the supplier maintained on file by the Quality Assurance Manager Incoming Goods Log Bill of Lading verifying each shipment came from an approved supplier Corrective action records 		