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SC Court of Appeals

THE STATE OF SOUTH CAROLINA
In The Court Of Appeals

APPEAL FROM THE ADMINISTRATIVE LAW COURT

THE HONORABLE H.W. FUNDERBURK, JR., ADMINISTRATE LAW JUDGE

CASE NO. 17-ALJ-17-0060-CC
APPELLATE CASE NO. 2019-001933

McEntire Produce, Inc., ...Respondent,

v.

South Carolina Department of Revenue, ...Appellant.

RECORD ON APPEAL

VOLUME III

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STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

McEntire Produce, Inc., Petitioner, vs. South Carolina Department of Revenue, Respondent.	)	Docket No. 17-ALJ-17-0060-CC **STIPULATIONS OF FACT**

Pursuant to ALC Rule 25(C), the Parties do hereby stipulate to the following:

1. McEntire Produce, Inc. (the "Petitioner") operates a produce processing facility in Columbia, South Carolina. The Petitioner processes lettuce, onions, cabbage, tomatoes, and other vegetables (hereinafter "produce") for sale. The Petitioner's produce processing includes, but is not limited to, washing, cutting, mixing, and packaging the finished produce at the Petitioner's facility.
2. On September 22, 2015, the South Carolina Department of Revenue (the "Department") initiated a sales and use tax audit of the Petitioner for tax periods October 1, 2012 through September 30, 2015 (the "Audit Period").
3. During the audit, the Department reviewed the Petitioner's purchase invoices and after discussing questionable items with the Petitioner determined that the Petitioner failed to report use tax on its purchases of numerous supplies and protective clothing. Accordingly, on July 19, 2016, the Department mailed the Petitioner a Proposed Assessment showing a total tax due in the amount of $126,912.90.[1]

[1]Between the issuance of the Department Determination and the hearing in this matter, the Parties were able to agree upon the taxability of some items in dispute. As such, the amount of disputed tax has been reduced from the amount listed in the Department Determination.



4. The supplies that remain at issue are attached to these Stipulations as Exhibit A.
5. On August 1, 2016, the Petitioner timely protested the Proposed Assessment due to the parties' disagreement as to whether the Petitioner's purchase of protective clothing and other supplies (see Exhibit A) are exempt from use tax.
6. While the parties disagree as to the taxability of the items at issue in the Proposed Assessment, the parties agree that the numerical figures and calculations reflected in the Proposed Assessment are accurate. Accordingly, the parties agree that the amount of tax in dispute is $82,305.83 (plus interest).
7. The Petitioner contends that tax periods October 1, 2012 through May 31, 2013 are time-barred.
8. The Petitioner timely requested a contested case hearing.
9. Dr. Gombas is an expert in the use of protective clothing for food safety purposes.
10. The parties stipulate that the deposition transcript of Dr. David Gombas may be used in these proceedings pursuant to Rule 32(a)(3)(B), SCRCP.
11. The parties stipulate to the admissibility of Petitioner's Exhibits 5, 7 – 8, 10 – 11, 14, 16 – 17, and 19 – 25. These exhibits along with Petitioner's complete Exhibit List are attached to these Stipulations as Exhibit B.
12. The parties stipulate to the admissibility of Respondent's Exhibit 1, which is attached to these Stipulations as Exhibit C.
13. The parties stipulate that if the Court determines that some of the items at issue are subject to tax while other items are exempt, this matter should be remanded back to the Department to calculate the tax and interest due on the items deemed taxable by the Court.

The Parties so stipulate:

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Columbia, South Carolina
November 14, 2018

EXHIBIT A

Stipulations of Fact
McEntire Produce, Inc. v. SC DOR
17-ALJ-17-0060-CC

McEntire Produce, Inc. v. SC DOR

17-ALJ-17-0060-CC

Supplies at Issue

1. Coveralls
2. Eyewear
3. Floor drain covers
4. Warning signs and stickers
5. Gloves
6. Aprons
7. Hairnets
8. Towels
9. Refrigerator in quality assurance lab
10. Blower fan
11. Lamps
12. Warehouse racks
13. Stacking containers
14. Forklift batteries
15. Forklift parts
16. Forklift repair parts
17. Forklift rental
18. Pallet jack
19. Pallet flow brakes
20. Generator rental
21. Bar code scanner
22. Black ink aerosol cans
23. Cleaning machines
24. Plastic shelves for maintenance parts room
25. Maintenance tools
26. Utility cart for maintenance tools
27. Oil lubricant for handtrucks and pallets
28. Cut wheel and disc maintenance tools
29. Brooms
30. Floor treatment chemicals
31. Squeegees
32. Mobile computer stand
33. White boards in production offices
34. Drug test kits
35. Storage water tank

EXHIBIT B

Stipulations of Fact
McEntire Produce, Inc. v. SC DOR
17-ALJ-17-0060-CC

McEntire Produce, Inc. v. SC DOR
17-ALJ-17-0060-CC

Petitioner's Exhibit List

1	FDA published guidance re: application of Part 117 to Listeria	McEntire0001-85
2	Dressing PowerPoint procedure	McEntire0215-216
3	Gombas summary	McEntire0519, 1971-1973
4	Facility Temperature	McEntire0540-541
5	Conventional product receiving	McEntire0542-543
6	Maintenance SOP	McEntire0537-539
7	HACCP reports	McEntire0565-573
8	Site Diagram	McEntire0581-583
9	Filter exchanges	McEntire1974-1985
10	Food safety plans	McEntire1986-2019
11	2015 BRC Audit Report	McEntire1903-1970
12	2016 BRC Audit Report	McEntire2092-2128
13	2018 BRC Audit Report	McEntire1822-1863
14	GMP PowerPoint Presentation	McEntire2129-2180
15	Proper Dress Procedure Video	N/A
16	Uniform	N/A
17	DOR email re: statute of limitations extensions	DOR 62-64
18	SOP GMP guidelines	DOR 88-96
19	SOL extensions	DOR 297-299
20	DOR's entire audit file in Respondent's possession and control	
21	Proposed Assessment	
22	Protest Letter	
23	Supplement to Protest – Position Statement	
24	Department Determination	
25	Deposition of Dr. Gombas	
26	Customer Spec Sheets	McEntire1794-1821
27	Department's Work Papers	

McEntire Produce

Conventional Product Receiving
Standard Operating Procedure 6.6

Approval			
Dept Mgr	Admin	QA Dir	Effective Date 7/31/09
Date	Date	Date	Author Steve Hoffert

Purpose: To describe the receiving and storage process for all raw produce to be processed, repacked or shipped whole case.

Scope: Receiving personnel will secure bill of ladings and check product as it is unloaded. After receiving they will also be responsible for proper storage.

Remarks: Receivers will need pens to fill out forklift checklists and put temp recorder information on each temp recorder (if no PO # is on the temp recorder from the supplier)

Procedure: The procedure will be as follows:

1. When the truck arrives at the gate they will be assigned a dock door by receiving.
2. The receiver will lock the trailer to the dock using the Pitt Bull system. The dispatchers will the get a Bill of Lading from the driver listing the goods to be received.
3. The dispatcher will stamp the BOL with the receiving stamp.
4. Labels will be printed by the dispatcher based off the BOL. Labels will have the PO # harvest and receive dates, weight, and country of origin, Lot # and pallet # on each label. Labels will be placed on the side of the pallet depending on which side of the rack the pallet is racked in.
5. Each bin to be stored in the racks must have an approved bin cap to protect the product from foreign material falling into it. The only approved bin caps at this time are the cardboard bin cap, or plastic bags. (Pictures below).





McEntire Produce

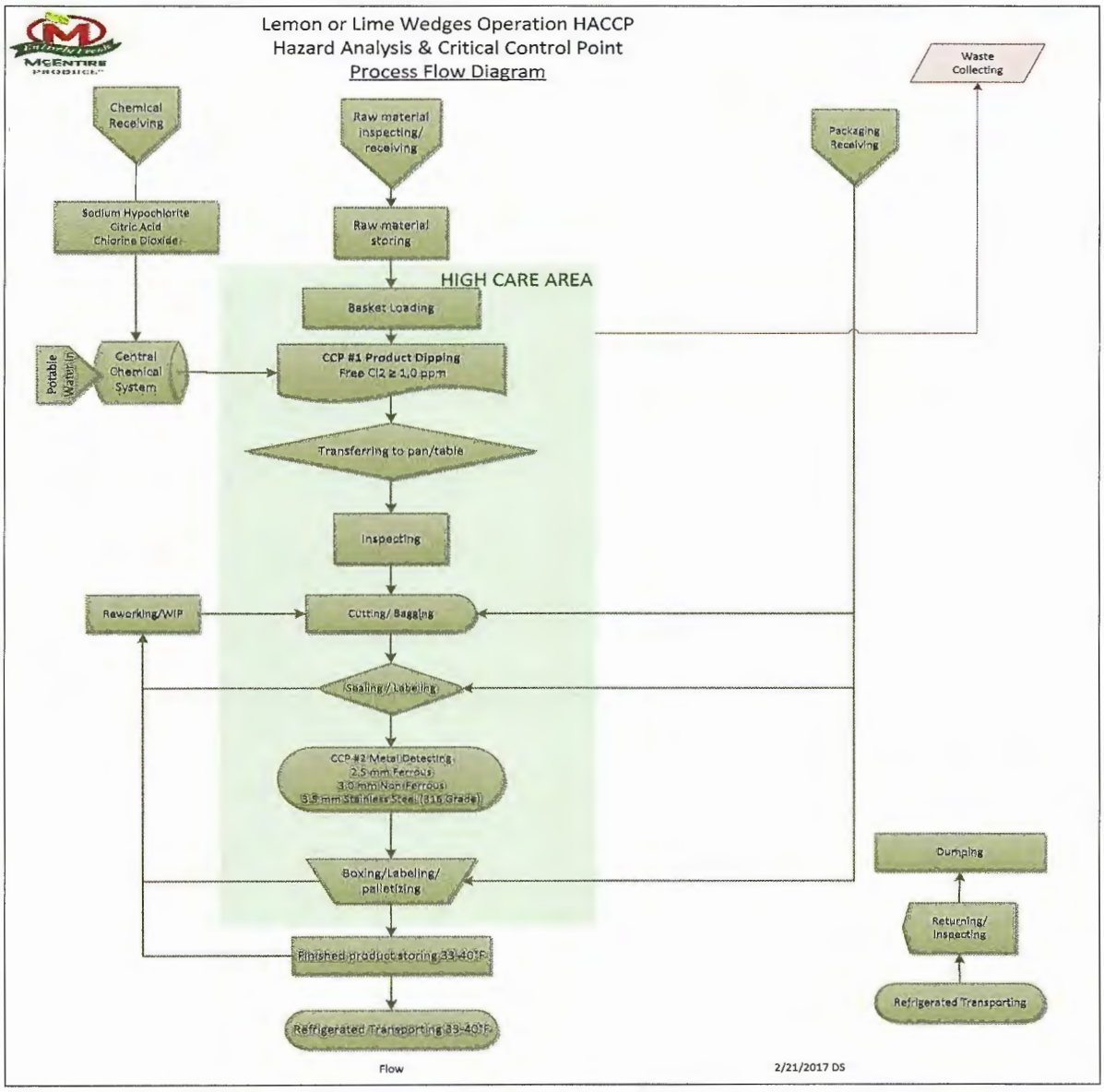
Conventional Product Receiving
Standard Operating Procedure 6.6

6. The receiver will then transfer the pallets to the designated store areas only after bin covers are in place.
7. All receiving BOL's will be turned in to the purchasing department.

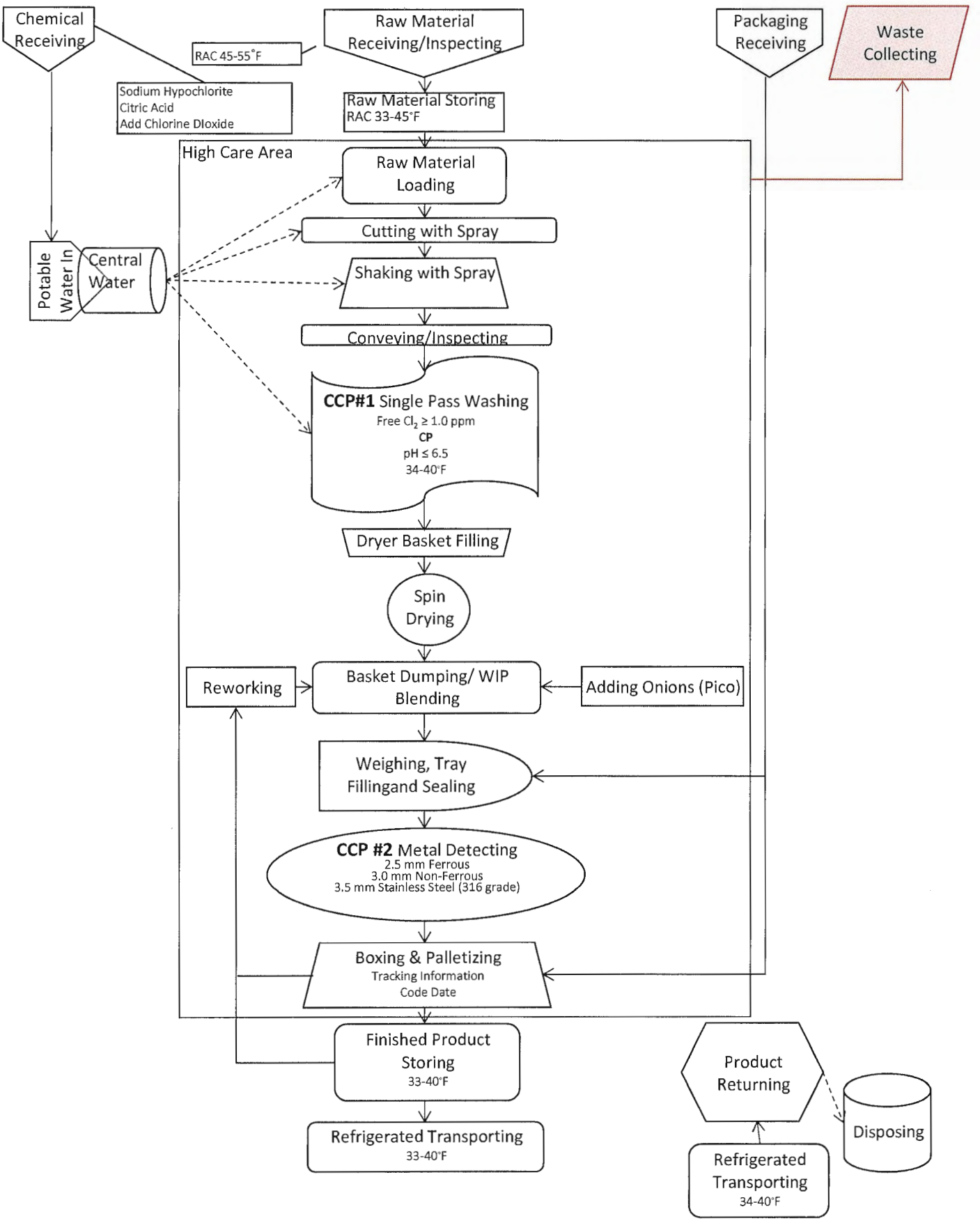
Training: Upon initial orientation, as needed and on an annual basis thereafter.

Records: Training Records are kept in the HR office.
Reference(s): none

Revision Log				
Date	**Rev**	**Changes**	**Justification**	**Author**
2/22/2017	8	Procedure #4	Review	Mark Pappas
2/18/16	7	Remarks and Procedure #7	Review	Mark Pappas
3/09/2015	6	None	Review	Mike Sexton
3/28/14	5	Procedure	Review	Mark Pappas
3/27/2014	4	None	Review	Mike Sexton
3/27/2013	3	Bin caps	New req.	Mike Sexton
10/22/12	2	None	Review	Mike Sexton
10/21/2011	1	Names	review	Mike Sexton
7/31/09				Steve Hoffert


Lemon or Lime Wedges Operation HACCP
Hazard Analysis & Critical Control Point
Process Flow Diagram
Waste Collecting
Chemical Receiving
Raw material inspecting/ receiving
Packaging Receiving
Sodium Hypochlorite
Citric Acid
Chlorine Dioxide
Raw material storing
HIGH CARE AREA
Basket Loading
Potable Water
Central Chemical System
CCP #1 Product Dipping
Free Cl2 ≥ 1.0 ppm
Transferring to pan/table
Inspecting
Reworking/WIP
Cutting/ Bagging
Sealing/Labeling
CCP #2 Metal Detecting
2.5 mm Ferrous
3.0 mm Non-Ferrous
3.5 mm Stainless Steel (316 Grade)
Dumping
Boxing/Labeling/ palletizing
Returning/ Inspecting
Finished product storing 33-40°F
Refrigerated Transporting
Refrigerated Transporting 33-40°F
Flow
2/21/2017 DS

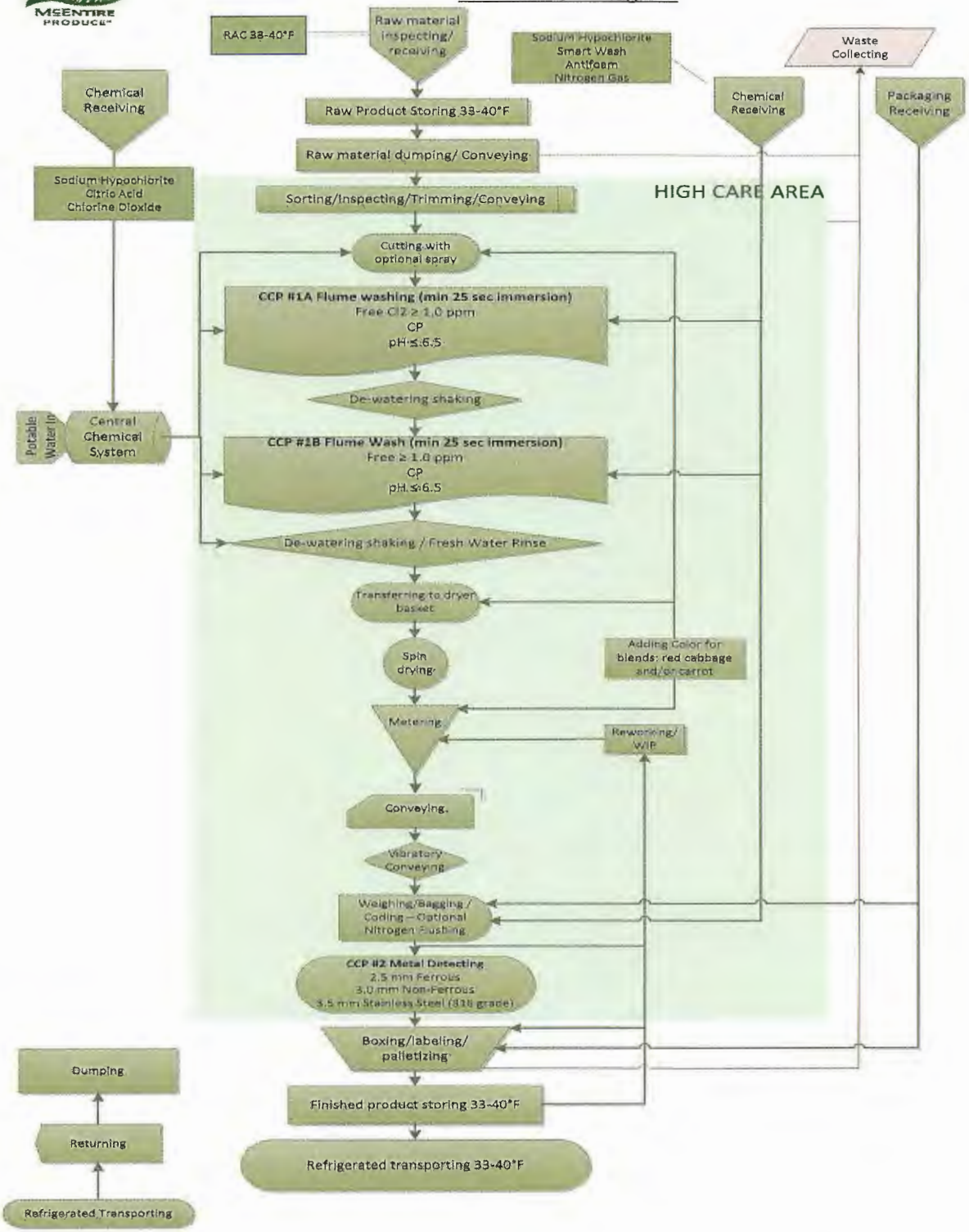
Line 9 Manual Pack



Flow

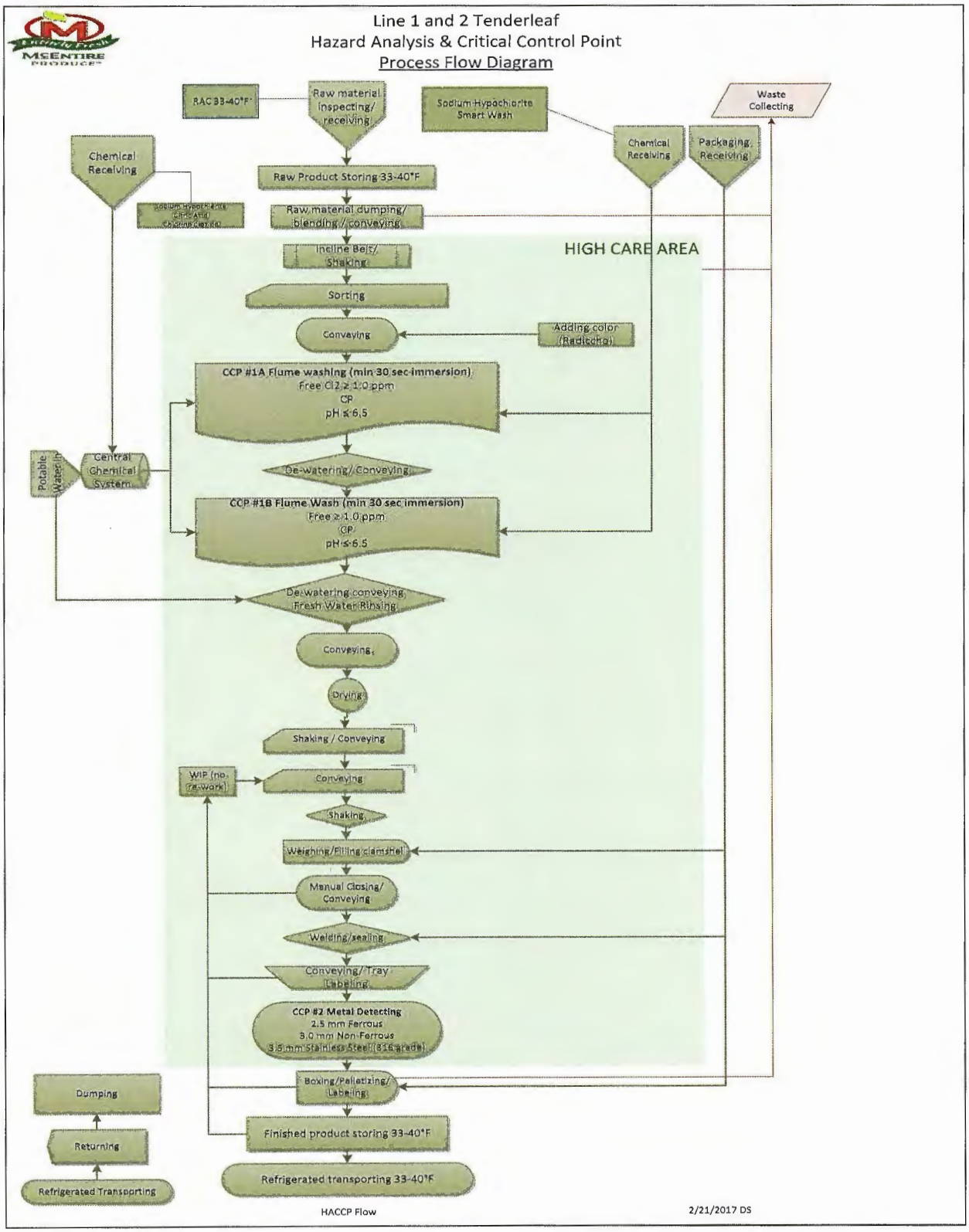
3/21/2017 DS

Line 4, 5, or 6
Hazard Analysis & Critical Control Point
Process Flow Diagram

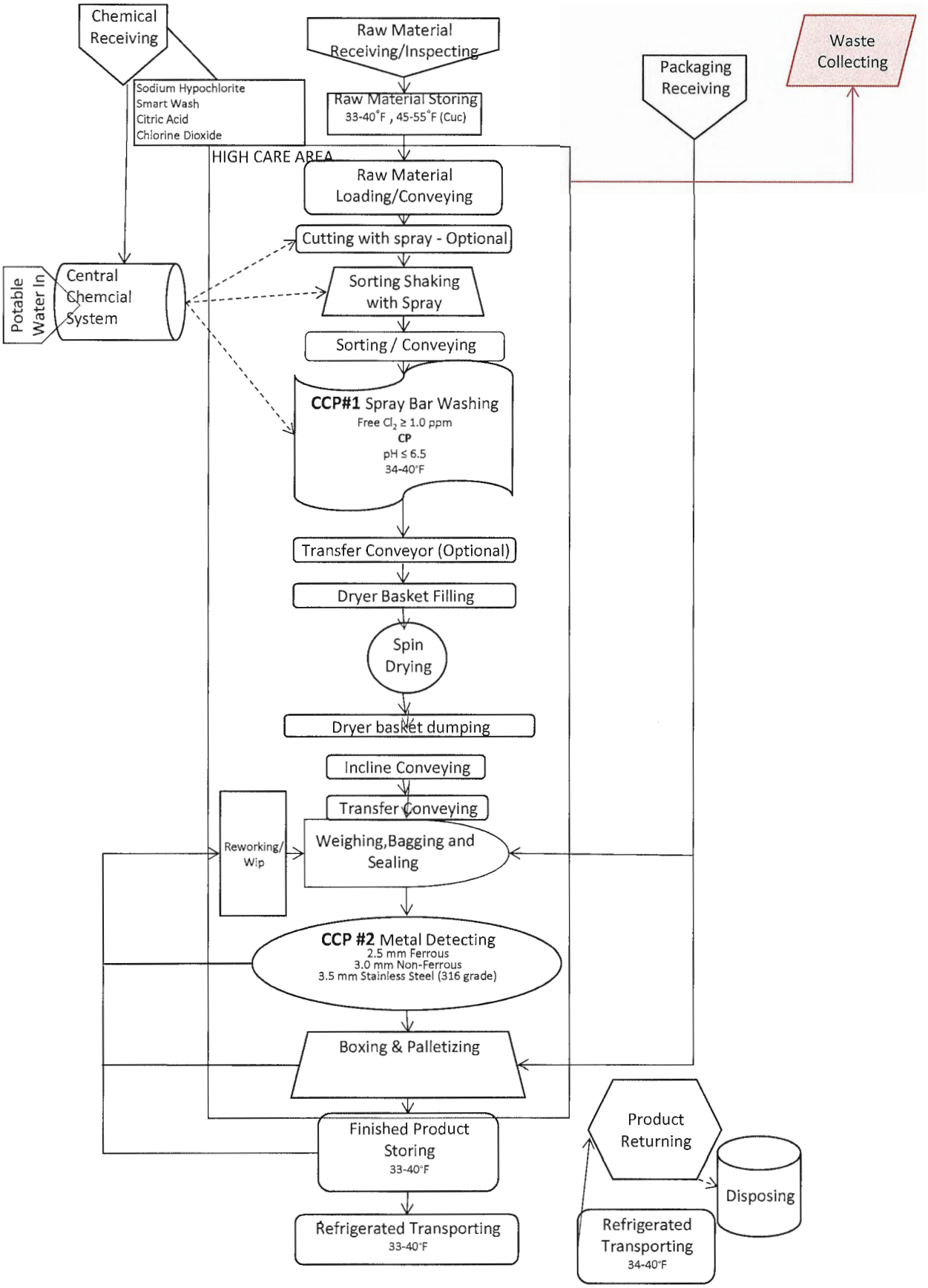


HACCP Flow

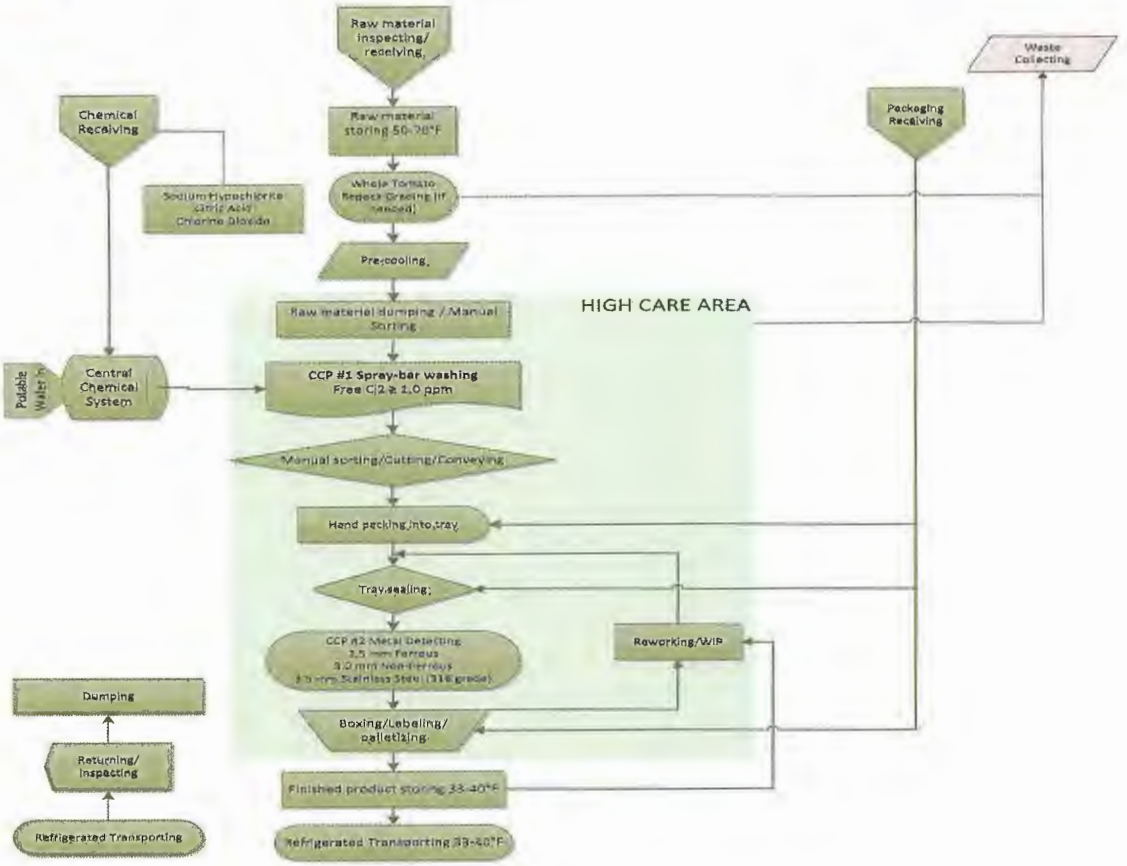
2/21/2017 HACCP DS


Line 1 and 2 Tenderleaf
Hazard Analysis & Critical Control Point
Process Flow Diagram
RAC 33-40°F
Raw material inspecting/ receiving
Sodium Hypochlorite Smart Wash
Waste Collecting
Chemical Receiving
Chemical Receiving
Packaging Receiving
Raw Product Storing 33-40°F
Sodium Hypochlorite (1ppm Free Available Chlorine Content)
Raw material dumping/ blending / conveying
HIGH CARE AREA
Incline Belt/ Shaking
Sorting
Conveying
Adding color (Radicchio)
CCP #1A Flume washing (min 30 sec immersion)
Free Cl2 ≥ 1.0 ppm
CP
pH ≤ 6.5
Potable Water In
Central Chemical System
De-watering/ Conveying
CCP #1B Flume Wash (min 30 sec immersion)
Free ≥ 1.0 ppm
CP
pH ≤ 6.5
De-watering conveying Fresh Water Rinsing
Conveying
Drying
Shaking / Conveying
WIP (no re-work)
Conveying
Shaking
Weighing/Filling clamshell
Manual Closing/ Conveying
Welding/sealing
Conveying/ Tray Labeling
CCP #2 Metal Detecting
2.5 mm Ferrous
3.0 mm Non-Ferrous
3.5 mm Stainless Steel (316 grade)
Boxing/Palletizing/ Labeling
Dumping
Returning
Refrigerated Transporting
Finished product storing 33-40°F
Refrigerated transporting 33-40°F
HACCP Flow
2/21/2017 DS

Line 9 HACCP Process Flow

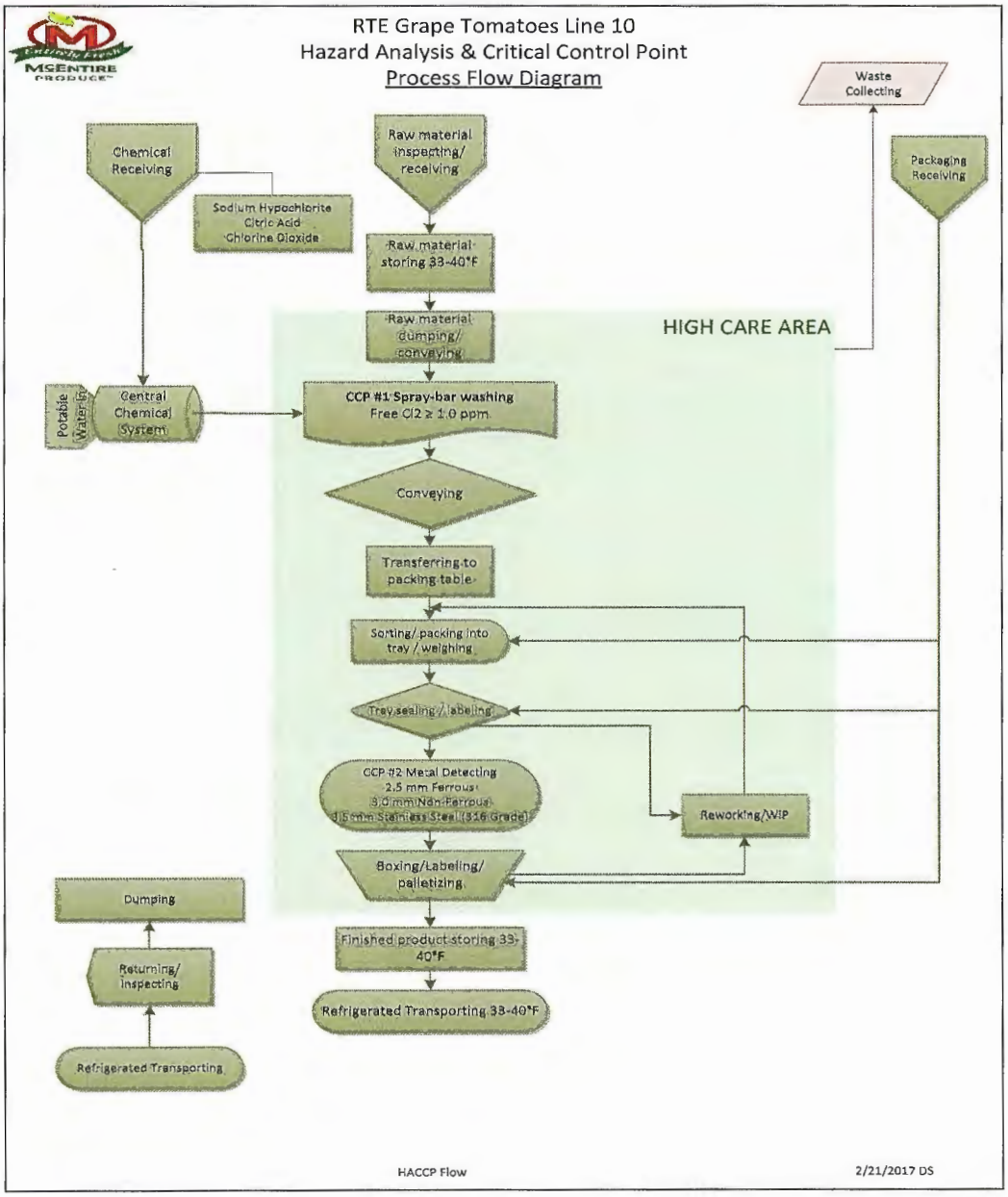


Line 10 Sliced Tomatoes
Hazard Analysis & Critical Control Point
Process Flow Diagram

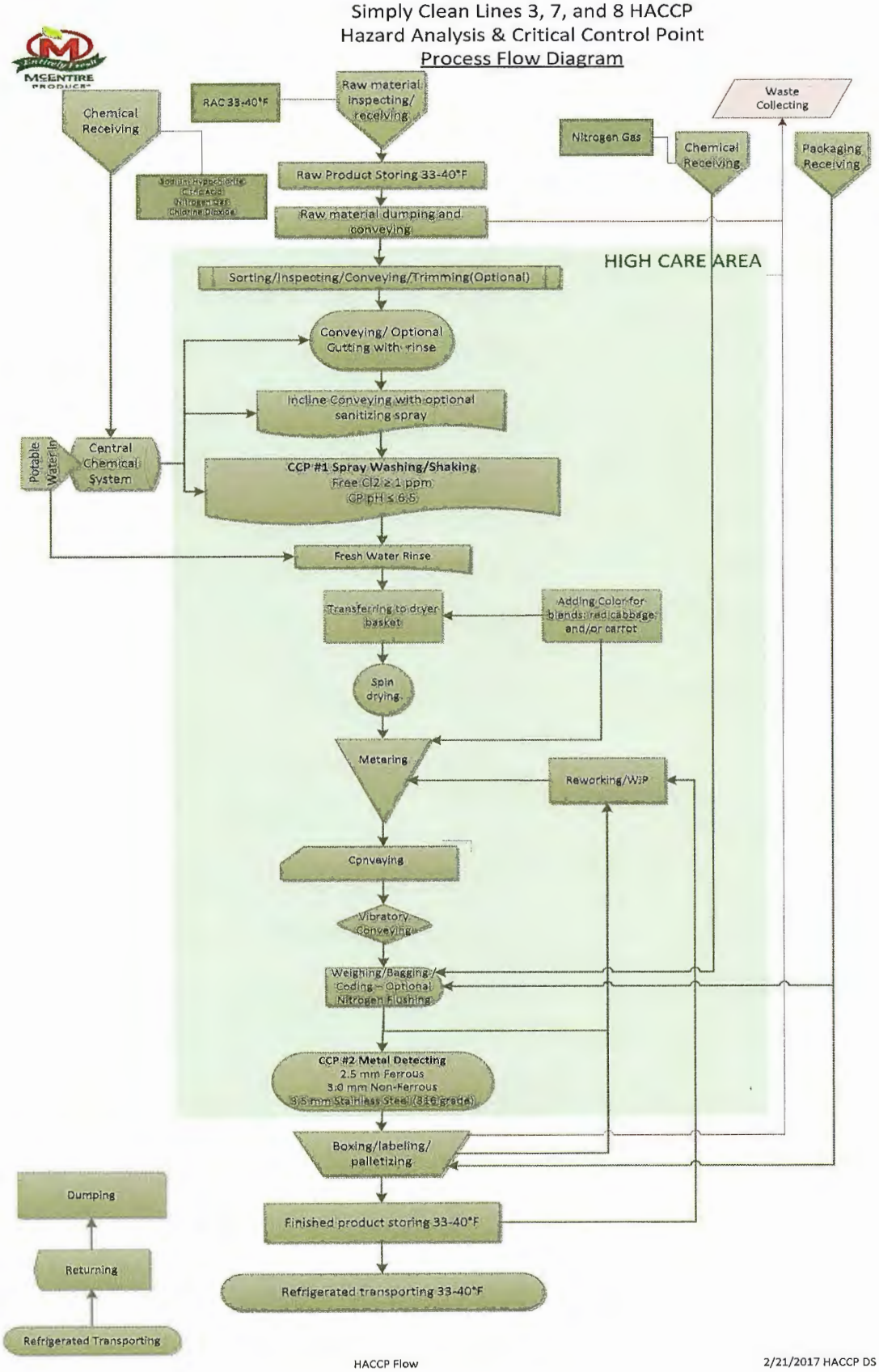


Flow

2/21/2017 DS

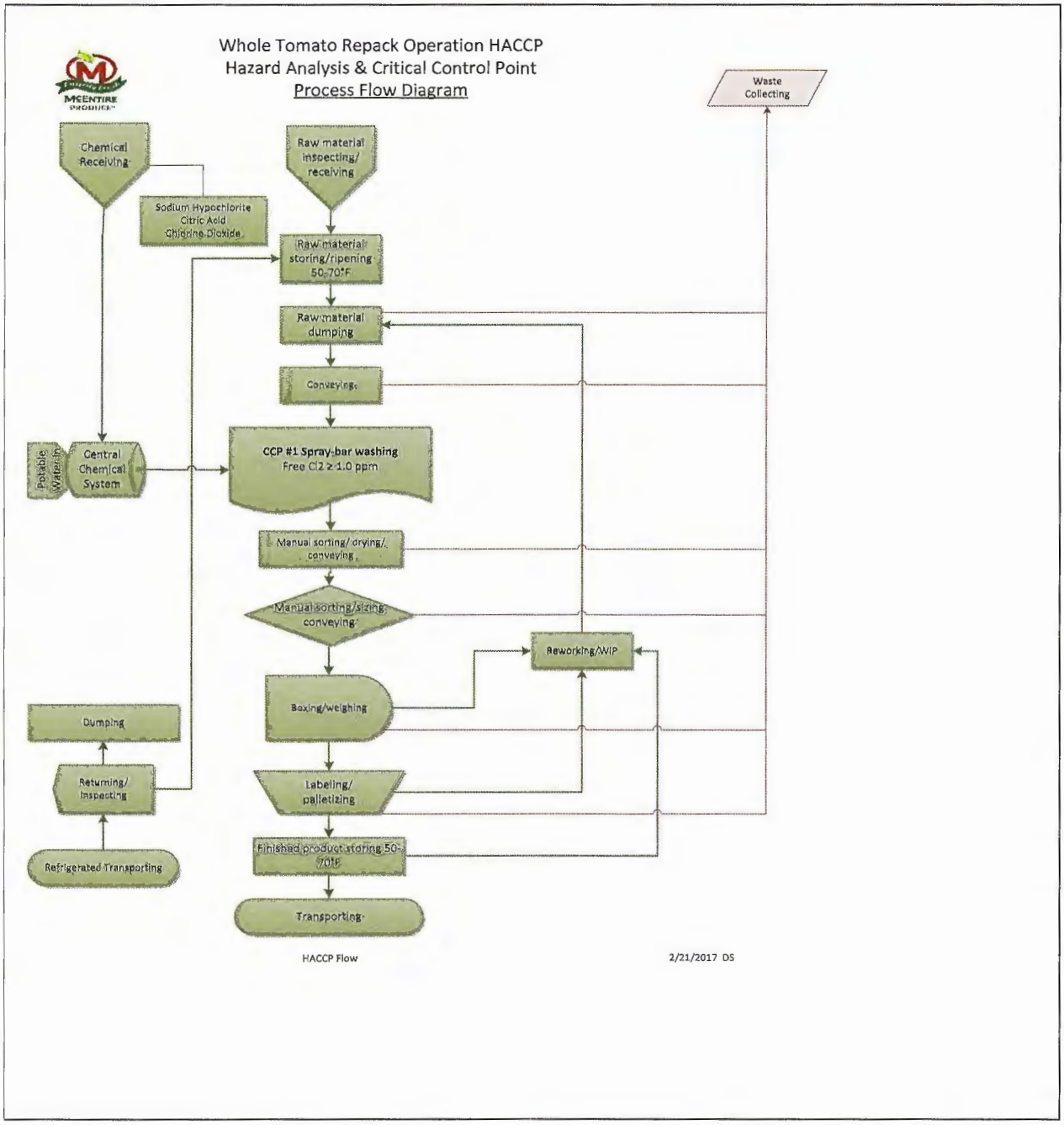

RTE Grape Tomatoes Line 10
Hazard Analysis & Critical Control Point
Process Flow Diagram
McENTIRE PRODUCE
Waste Collecting
Chemical Receiving
Raw material inspecting/ receiving
Packaging Receiving
Sodium Hypochlorite
Citric Acid
Chlorine Dioxide
Raw material storing 33-40°F
HIGH CARE AREA
Raw material dumping/ conveying
Potable Water
Central Chemical System
CCP #1 Spray-bar washing
Free Cl2 ≥ 1.0 ppm
Conveying
Transferring to packing table
Sorting/packing into tray / weighing
Tray sealing / labeling
CCP #2 Metal Detecting
2.5 mm Ferrous
3.0 mm Non-Ferrous
3.5 mm Stainless Steel (316 Grade)
Reworking/WIP
Boxing/Labeling/ palletizing
Dumping
Finished product storing 33-40°F
Returning/ Inspecting
Refrigerated Transporting 38-40°F
Refrigerated Transporting
HACCP Flow
2/21/2017 DS

Simply Clean Lines 3, 7, and 8 HACCP Hazard Analysis & Critical Control Point Process Flow Diagram



HACCP Flow

2/21/2017 HACCP DS


Whole Tomato Repack Operation HACCP
Hazard Analysis & Critical Control Point
Process Flow Diagram
Waste Collecting
Chemical Receiving
Raw material inspecting/ receiving
Sodium Hypochlorite
Citric Acid
Chlorine Dioxide
Raw material storing/ripening 50-70°F
Raw material dumping
Conveying
Potable Water In
Central Chemical System
CCP #1 Spray-bar washing
Free Cl2 ≥ 1.0 ppm
Manual sorting/ drying/ conveying
Manual sorting/sizing conveying
Reworking/WIP
Boxing/weighing
Dumping
Returning/ Inspecting
Labeling/ palletizing
Refrigerated Transporting
Finished product storing 50-70°F
Transporting
HACCP Flow
2/21/2017 DS

Site Plan Diagram

High Care-Low Care, Personnel, Waste, WIP, and Rework Flow Diagram

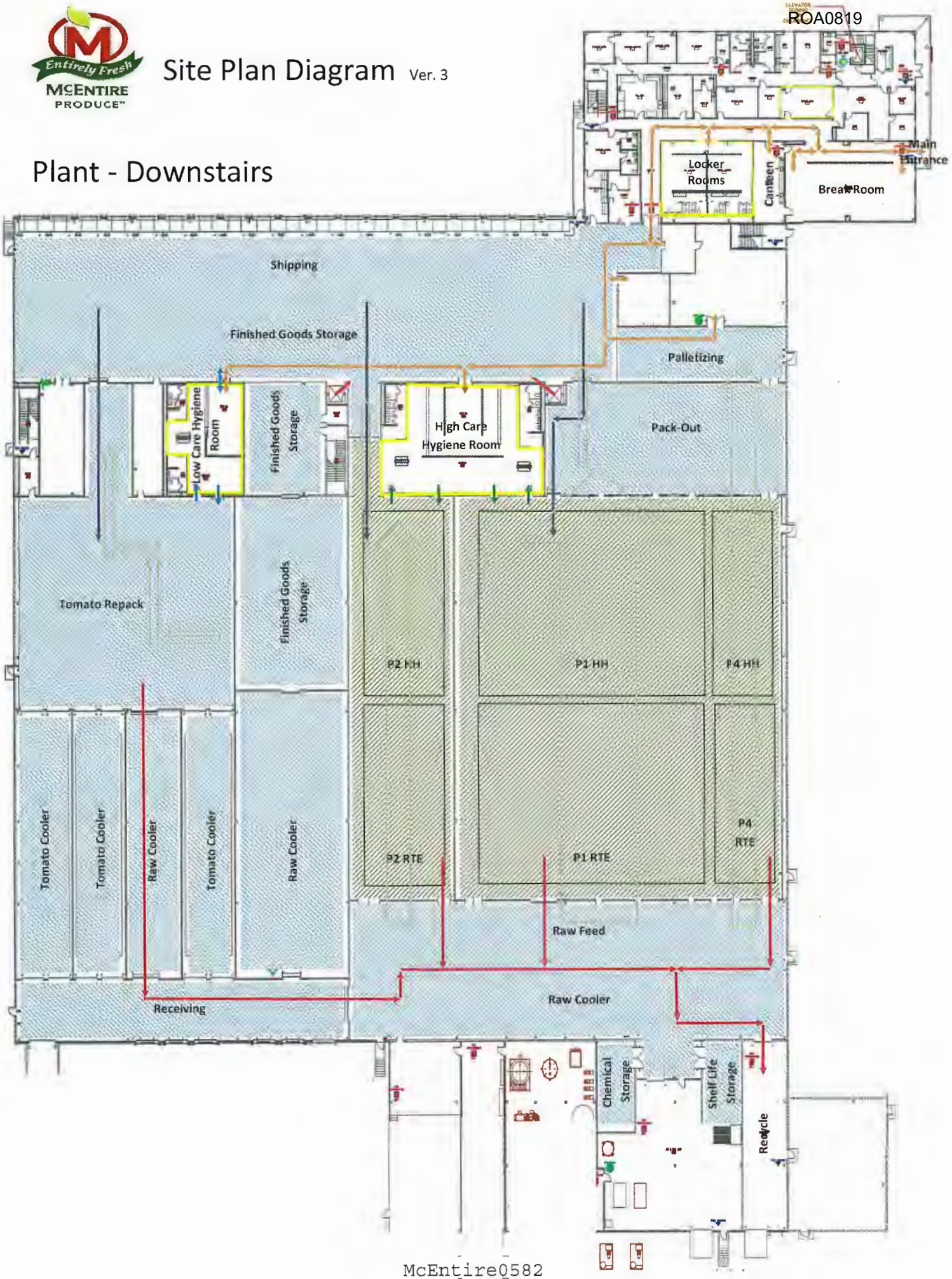
Color Legend:

	High Care Area
	Low Care Area
	Personnel Travel Route
	High Care Entry/Exit
	Low Care Entry/Exit
	WIP/Rework Transport
	Production Waste Transport
	Processing Flow

Revision Log				
Date	**Rev. #**	**Changes**	**Justification**	**Reviser**
11/29/2012	0	New Document		Hari Thakur
08/21/2013	1	Split P3	Isolate Onion Peel	Diana Simpson
04/27/2015	2	Move P2	Remove Onion Peel	Diana Simpson
1/4/2015	3	Formatting		Diana Simpson
11/17/2016	4	Review		Diana Simpson

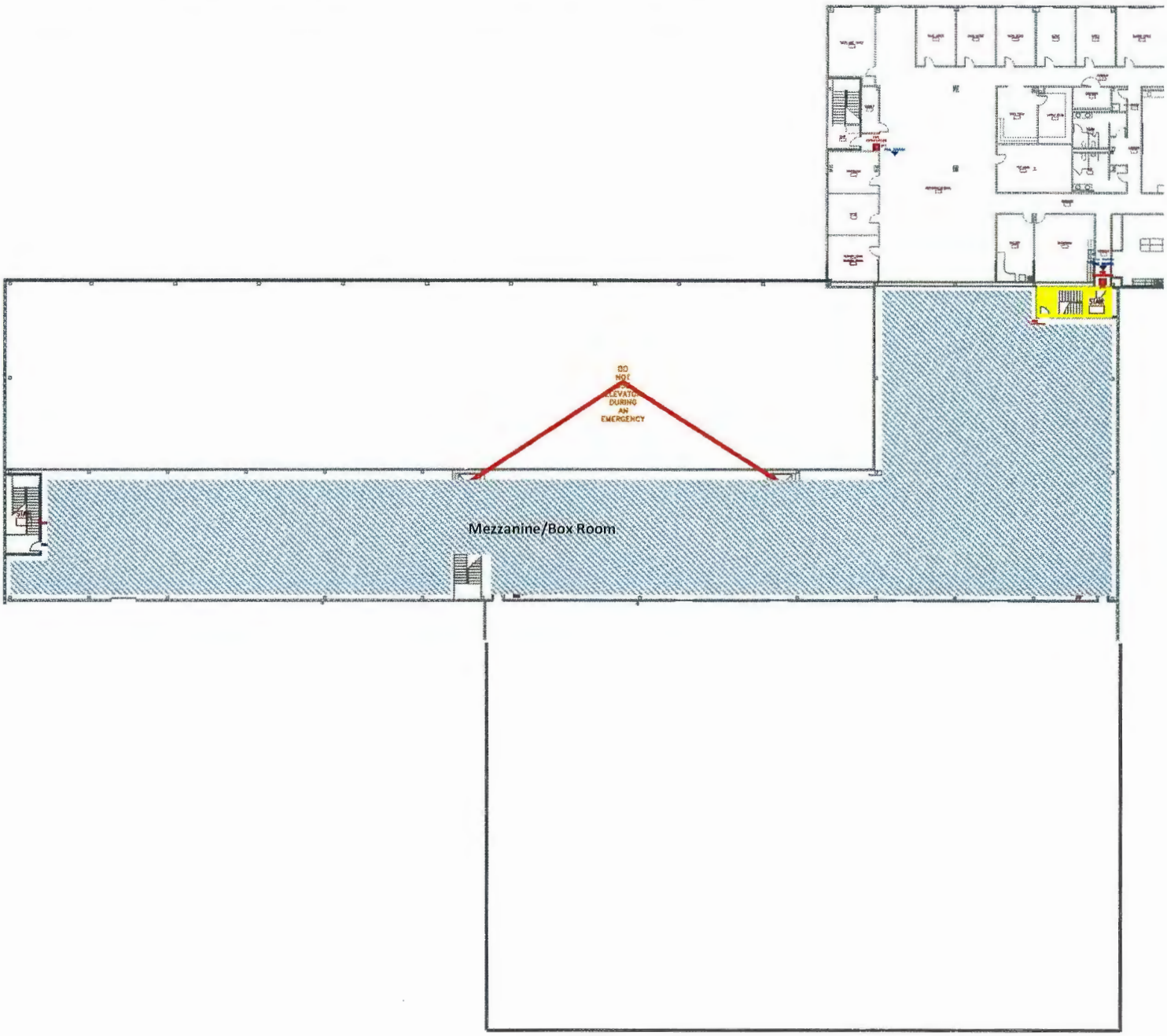
Site Plan Diagram Ver. 3

Plant - Downstairs



Site Plan Diagram Ver. 3

McEntire Produce – Second Floor





FOOD SAFETY PLANS

McEntire Produce
2040 American Italian Way
Columbia, SC 29209
Processed and Washed Produce Items

ISSUE DATE: 2/14/2018
SUPERSEDES: 1/21/2018

Food Safety Plan for Processed and Washed Produce Items

Company Overview

This year-round fresh-cut processing and repacking facility was built in 2007. The facility is 163,000 sq.ft and has an average of 600 employees. A variety of fresh cut vegetable products are processed or repacked to meet customer requirements and specifications. The majority of fresh cut product is processed for food service customers, and a smaller portion is for retail sales. Some of the retail product is processed under a co-packing agreement, in which the product and the equipment is owned by Organic Girl Corporation, based in California. Product is produce up to 6 days a week, with one to two production shifts and a daily sanitation shift. All ingredients and materials are sourced from approved suppliers.

Food Safety Team

NAME	POSITION
Carter McEntire	CEO / President
Tom Lovelace*	Executive Vice President
Dave Morris	Sr. Vice President, Operations
Kim Pham*	Quality Assurance Director
Daniel Aderhold	Quality Engineer Manager
Waunda Wright	Quality Assurance Supervisor
Wayne Bailey*	Food Safety Director
OPEN	Food Safety Manager
Stephanie Blazer	Food Safety Supervisor
Eric Moulton	Director of Facilities
Luis Ramirez	Maintenance Director
Bobby Coggins	Repack Director
Rudy Branham	Processing Director
Mike Sexton	Vice President, Supply Chain

*Preventive Controls Qualified Individual

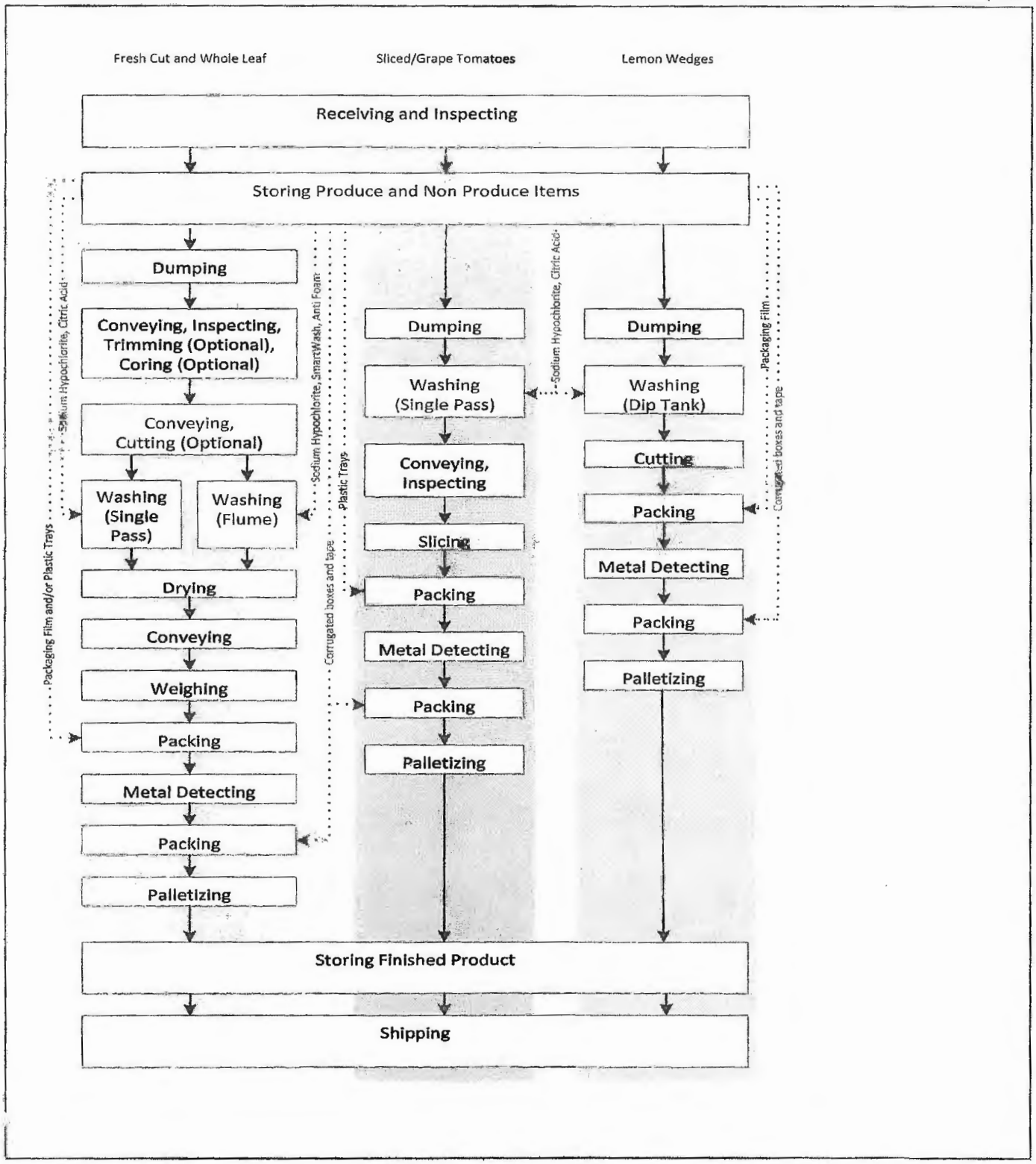
McEntire Produce
2040 American Italian Way
Columbia, SC 29209
Processed and Washed Produce Items

ISSUE DATE: 2/14/2018
SUPERSEDES: 1/21/2018

Product Description

Product Name(s):	Fresh Cut Produce Items
Product Description, including Important Food Safety Characteristics:	Refrigerated, washed and ready-to-eat fresh cut produce items
Ingredients:	May contain iceberg lettuce, green leaf lettuce, red leaf lettuce, romaine lettuce, spinach, kale, spring mix, carrots, cabbage, tomatoes, peppers, onions, cucumbers, carrots, lemons, radicchio, radish
Allergens:	None in product
Packaging Used:	Bag film or plastic clams packed in corrugated boxes
Intended Use:	Ready to eat produce items for retail and foodservice
Intended Customers:	General Public
Shelf Life:	Use by 10-14 days after manufacture date
Labeling Instructions:	Keep refrigerated (temperature range 34-40°F or 34-40°F on carton)
Other Labeling (as applicable):	Julian Date, Use by date, Organic/Kosher, Country of Origin
Storage and Distribution:	Refrigerated (33-40°F) storage and distribution

Flow Diagram



McEntire Produce
2040 American Italian Way
Columbia, SC 29209
Processed and Washed Produce Items

ISSUE DATE: 2/14/2018
SUPERSEDES: 1/21/2018

Process Narrative

Receiving and Inspecting		Bulk raw and pre-washed produce items are received precooled from approved suppliers and verified at receipt. All grower suppliers are pre-verified compliant with the Produce Safety rule. Produce brokers are required to demonstrate all raw produce is from growers compliant with the Produce Safety rule. Produce is inspected for quality per receiving specifications and accepted or rejected. Non-produce materials such as chemicals, packaging, labels, tape, etc. are received from approved suppliers and inspected on receipts.
Storing Produce and Non Produce Items		Produce is stored in an on-site cooler at appropriate and monitored temperatures up to a maximum number of days per commodity specification. Product is used by harvest date (oldest first), except as needed per product/customer specification. Non-produce materials are stored per supplier recommendation and any pertinent regulation.
Fresh Cut and Whole Leaf Processing		
	Dumping	Bins and totes of raw produce material are dumped onto a conveyor and transferred into the high care processing area.
	Conveying, Inspecting, Trimming (Optional),	Product is conveyed and inspected by workers or an optical sorter. Trimming and Coring is done as needed.
	Conveying , Cutting (Optional)	Product is conveyed and cut as required before entering the wash system.
	Washing - Single Pass	Product enters a Simply Clean wash system and washed with single pass chilled water (<39°F) that contains sodium hypochlorite and a buffer solution (citric acid or smartwash) to keep a minimum free active chlorine level of 1ppm and the pH ≤6.5. The chemicals are injected and monitored continuously via a PLC system with pumps and calibrated probes. The PLC system will shut down the feed belt to the wash system if chemicals fall outside of set limits.
	Washing - Flume	Product enters a double pass flume wash system and washed with chilled water (<39°F) that contains sodium hypochlorite and a buffer solution (citric acid or smartwash) to keep a minimum free active chlorine level of 1ppm and the pH ≤6.5. The chemicals are injected and monitored continuously via a PLC system with pumps and calibrated probes. The PLC system will shut down the feed belt to the wash system if chemicals fall outside of set limits. Water in the flume system is recirculated, filtered to remove large pieces and replenished as needed. The end of each pass of the flume has a dewatering shaker to remove excess water. A fresh water spray is delivered to the produce on the dewatering shaker on the second pass.

	Drying	The product is collected into a dryer basket and prewashed items (carrots, cabbage, etc.) are added in if required product specific blends. The dryer baskets are placed into a centrifugal spin dryer for a commodity-specific, programmed spin and then manually dumped into a hopper.
	Conveying	Product is conveyed to the scale.
	Weighing	The scale weighs and gravity dispenses the product to the packaging unit.
	Packing	The product is collected into a tray or bag and sealed. Product lot codes and use by dates are printed on the film for bags or labels that are affixed to the clam shells. Other labeling is preprinted on packaging or labels.
Sliced/Grape Tomatoes		
	Dumping	Boxes of precooled, color sorted and pre-sized tomatoes are manually dumped onto a conveyor in the high care processing room.
	Washing (Single pass)	Tomatoes are spray rinsed with single pass chilled water (<39°F) containing a minimum free chlorine level of 1ppm with a ph ≤6.5. The chemicals are injected and monitored continuously via a PLC system with pumps and calibrated probes.
	Conveying, Inspecting	Tomatoes are manually inspected and culls moved to a waste conveyor.
	Slicing	Tomatoes are placed on a manual slicer and sliced.
	Packing	Sliced tomatoes are manually placed in open tray with absorbent pad and heat sealed. Product is labeled per customer specification.
Lemon Wedges		
	Dumping	Boxes of lemons are manually dumped into a basket in the high care processing room.
	Washing (Dip tank)	Lemons are dipped in a tank of wash water containing a minimum free chlorine level of 1ppm with a ph ≤6.5. The water is manually monitored to ensure correct chemical range.
	Cutting	The basket is manually transferred to the cutting station. Lemons are placed on a manual slicer and cut into wedges.
	Packing	The wedges are manually placed into a bag and heat sealed. Product is labeled per customer specification.
Metal Detecting		Packaged product is passed through a calibrated fully functional metal detector. Rejected product is inspected and corrective action taken per metal detection policy.
Packing		Product is packed into corrugated cardboard boxes per customer specification and sealed with tape.
Palletizing		Boxes are palletized and pallet tags are affixed for traceability.
Storing Finished Product		Palletized product is stored in the finished good coolers until shipping.

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Shipping	Product is picked manually and re-palletized as needed to meet customer orders. Product is loaded onto company owned or 3rd party pre-cooled trucks.

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Hazard Analysis

The potential food safety hazards identified 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, including potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

(1) Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Is a preventive control required for potential hazard? Yes	(3) No	(4) Justification for decision in column 3	(5) What preventive control measure(s) can significantly minimize or prevent the hazard?	(6) Is the preventive control applied at this step? Yes	(6) No
Receiving and Inspecting (Produce Items)	B	Salmonella, L. monocytogenes, EHEC, pathogenic viruses and parasites	X		Fresh produce has been linked to foodborne illness due to human and environmental pathogens	Supply-chain Control, Produce temperature checks against specification - reject if not in compliance	X	
	C	Pesticide, agricultural chemicals	X		Pesticides and chemicals unlikely for items sourced domestically, but potential exist in imported produce	Supply-chain Control for imported produce	X	
		Allergens		X	No allergens in products			
	P	Hard, shop objects or choking hazards		X	Subsequent inspection and sorting make this unlikely			
Receiving and Inspecting	B	None						

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Inspecting (Non-produce Items)	C	Wrong chemical or packaging		X	All chemicals and food-contact packaging is approved for use and all non-produce materials are sourced from approved suppliers.			
	P	None						
Storing (Produce Items)	B	Cross-contamination		X	GMP's make hazards during storage unlikely to occur. Items stored covered and physical hazards unlikely to pass subsequent inspections and sorting.			
	C	Sanitation Chemicals		X				
	P	Wood and other debris from damaged pallets, bins and totes.		X				
Storing (Non-produce Items)	B	None		X	GMP's make hazards during storage unlikely to occur. Items stored covered and physical hazards unlikely to pass subsequent inspections and sorting. Storage temperatures monitored.			
	C	Contamination with hazardous chemicals		X				
	P	Wood and other debris from damaged pallets, bins and totes.		X				
Fresh Cut and Whole Leaf - **Dumping**	B	Pathogens from		X	GMP procedures make			
	C	None						
	P	Wood and other debris from damaged pallets, bins and totes.		X	Unlikely to pass subsequent inspections and sorting			
Fresh Cut and Whole Leaf - **Conveying,**		Pathogens from human contact, contaminated utensils		X	Unlikely with GMP procedures			

Inspecting, Trimming (Opt.) Coring (Opt.)	B	Environmental pathogens (L. monocytogenes)	X		This step separates raw from processed product. Enhanced sanitation warranted from here through packaging.	Master sanitation program (SSOPs) and Preoperational inspection program	X	
	C	None						
	P	Broken knives	X		Unlikely to go unnoticed during manual coring, trimming and metal detection.			
Fresh Cut and Whole Leaf - **Conveying, Cutting (Opt.)**	B	Environmental pathogens (L. monocytogenes)	X		Enhanced attention to sanitation warranted	Master sanitation program (SSOPs) and Preoperational inspection program	X	
	C	None						
	P	Broken blades, metal fragments	X		Metal fatigue can cause breakage	Metal Detector		X
Fresh Cut and Whole Leaf - **Washing (Single Pass)**	B	Cross-contamination		X	Single pass wash makes this an unlikely source of pathogens or cross-contamination			
		Environmental pathogens (L. monocytogenes)	X		Enhanced attention to sanitation warranted	Master sanitation program (SSOPs) and Preoperational inspection program	X	
	C	None						
	P	None						
Fresh Cut and Whole Leaf - **Washing (Flume)**		Cross-contamination	X		Recirculated wash water could results in cross-contamination if chemicals are not appropriate strength	Control of free Chlorine in water	X	

	B	Environmental pathogens (L. monocytogenes)	X		Enhanced attention to sanitation warranted, wash water temperature controlled	Master sanitation program (SSOPs) and Preoperational inspection program, automated and manual wash water temperature checks	X	
	C	Off-gassing and legal limits of chlorine use		X	Unlikely to occur and go unnoticed			
	P	None						
Fresh Cut and Whole Leaf - **Drying**	B	Environmental pathogens (L. monocytogenes), cross-contamination	X		Enhanced attention to sanitation warranted	Master sanitation program (SSOPs) and Preoperational inspection program	X	
	C	None						
	P	None						
Fresh Cut and Whole Leaf - **Conveying**	B	Environmental pathogens (L. monocytogenes), cross-contamination	X		Enhanced attention to sanitation warranted	Master sanitation program (SSOPs) and Preoperational inspection program	X	
	C	None						
	P	None						
Fresh Cut and Whole Leaf - **Weighing**	B	Environmental pathogens (L. monocytogenes), cross-contamination	X		Enhanced attention to sanitation warranted	Master sanitation program (SSOPs) and Preoperational inspection program	X	
	C	None						
	P	Metal Fragments from fatigue	X			Metal detector		X
Fresh Cut and Whole Leaf - **Packaging**	B	Environmental pathogens (L. monocytogenes), cross-contamination	X		Enhanced attention to sanitation warranted	Master sanitation program (SSOPs) and Preoperational inspection program	X	
	C	Chemical residues on packaging		X	Unlikely to occur			
	P	None						

Sliced/ Grape Tomatoes - **Dumping**	B	Pathogens from human contact		X	Unlikely with GMPs			
	C	None						
	P	Foreign materials from boxes		X	Subsequent inspection and sorting make this unlikely			
Sliced/ Grape Tomatoes - **Washing (Single Pass)**	B	Pathogen cross-contamination		X	Single pass shower makes this an unlikely source of pathogens or cross contamination, wash water temperature checks			
	C	None						
	P	None						
Sliced/ Grape Tomatoes - **Conveying, Inspecting**	B	Environmental pathogens (L. monocytogenes)	X		Enhanced attention to sanitation warranted	Master sanitation program (SSOPs) and Preoperational inspection program	X	
		Pathogens from human contact		X	Unlikely with GMPs			
	C	None		X				
	P	None		X				
Sliced/ Grape Tomatoes - **Slicing**	B	Environmental pathogens (L. monocytogenes)	X		Enhanced attention to sanitation warranted	Master sanitation program (SSOPs) and Preoperational inspection program	X	
		Pathogens from human contact		X	Unlikely with GMPs			
	C	None						
	P	Metal breakage from slicer		X	Unlikely to break without being noticed.			
Sliced/ Grape Tomatoes - **Packing**	B	Pathogens from human contact		X	Unlikely with GMPs			
	C	None						
	P	None						
Lemon Wedges -	B	Pathogens from human contact		X	Unlikely with GMPs			
	C	None						

Dumping	P	Foreign materials from boxes		X	Subsequent inspection and sorting make this unlikely			
Lemon Wedges - **Washing (Dip Tank)**	B	Cross-contamination	X		Recirculated wash water could results in cross-contamination if chemicals are not appropriate strength	Control of free Chlorine in water	X	
		Environmental pathogens (L. monocytogenes)	X		Enhanced attention to sanitation warranted	Master sanitation program (SSOPs) and Preoperational inspection program	X	
	C	Off-gassing and legal limits of chlorine use		X	Unlikely to occur and go unnoticed			
	P	None						
Lemon Wedges - **Cutting**	B	Environmental pathogens (L. monocytogenes)	X		Enhanced attention to sanitation warranted	Master sanitation program (SSOPs) and Preoperational inspection program	X	
		Pathogens from human contact		X	Unlikely with GMPs			
	C	None						
	P	Metal breakage from slicer		X	Unlikely to break without being noticed.			
Lemon Wedges - **Packing**	B	Pathogens from human contact		X	Unlikely with GMPs			
	C	None						
	P	None						
Metal Detecting	B	None						
	C	None						
	P	Metal if detector is not working, calibrated or skipped	X		Metal contamination can be detected at this point	Metal Detection	X	
Packing	B	None						
	C	None						
	P	None						
Palletizing	B	None						
	C	None						
	P	None						

Storing in inventory	B	Pathogen growth if temperature abused		X	Significant temperature abuse unlikely to go unnoticed, storage temperature automatically monitored per specifications			
	C	None						
	P	None						
Shipping	B	Pathogen growth if temperature abused		X	Significant temperature abuse unlikely to go unnoticed, shipping temperature automatically monitored per specifications			
	C	None						
	P	None						

Process Preventive Controls

Process Control Step		Control of free chlorine in wash water	Metal Detection
Hazard(s)		Pathogens cross-contamination	Undetected metal
Parameters values or critical limits		Minimum 1 ppm free chlorine in both wash tanks	Detector and Belt functioning properly for 3.5 mm stainless steel, 2.0 mm ferrous and 3.0 mm non ferrous
Monitoring	**What**	Free Chlorine concentration (ppm)	Metal Detector and Belt Timing
	How	Free Chlorine meter: turn meter on, rinse and fill cell with flume water sample, zero meter, add reagent to sample, read sample, record result displayed	Place each standard under or over a bag of product and pass through metal detector
	Frequency	Start-up, Approx. Hourly, Water change or wash down and End of Shift	Start-up, Approx. Hourly, Changeover, End of Shift
	Where	Wash Step	Metal Detector
	Who	QA Technicians	QA Technicians
Corrective Action		1) Stop Production 2) Isolate Product Since Last Good Check 3) Check wash system functionality 4) Adjust Chlorine 5) Discard product	1) Stop Production 2) Isolate Product Since Last Good Check 3) Adjust Metal Detector and/or Belt 4) Re-test product through verified working metal detector
Verification		HACCP monitoring, Daily verification sign off By HACCP certified QA/FS management	HACCP monitoring, Daily verification sign off By HACCP certified QA/FS management, Annual Manufacturer Servicing
Records		HACCP monitoring, Deviation Report, Food Safety Incident Report, Hold and Release or Dispose	HACCP monitoring, Deviation Report, Food Safety Incident Report, Hold and Release or Dispose

Supply Chain Preventive Controls Program

Hazards requiring a supply-chain applied control: Hazard analysis determined that human pathogens, such as Salmonella and STEC E.coli, are significant hazards for raw produce. There is a foreseeable risk of misuse of harmful agricultural chemicals, such as pesticides, in imported produce. These hazards are best controlled at the grower level
Preventive controls applied by the supplier: Compliance by the grower with the Produce Safety rule minimizes the risk of contamination with human pathogens. Compliance with Good Agricultural Practices and U.S. MRLs minimizes the risk of contamination with harmful agricultural chemicals in imported produce.
Verification activities: McEntire Produce, or a 2nd/3rd party audit growers who supply our produce, by a qualified auditor, is used to verify compliance with the Produce Safety rule. Letters of guarantee are required from suppliers of prewashed onions and carrots that 1) they are in compliance with the Preventive Controls for Human Food rule, 2) they require their fresh produce suppliers to be in compliance with the Produce safety rule; and 3) they require importers of fresh produce to be in compliance with the Foreign Supplier Verification Program rule, including adequate control of the use of potentially harmful agricultural chemicals.

Verification procedures: A copy of a 3rd party audit is required to be available from all direct suppliers on an annual basis. When produce is supplied through an intermediate (broker or importer), the intermediate must provide a copy of a current 2nd or 3rd party audit report of the supplier, performed by a qualified auditor. The audit results are reviewed and follow up discussion with the supplier or the intermediate takes place as necessary, to verify that any corrective actions mentioned in the report have been completed.
Temporary approval for a new supplier may be granted if a copy of the supplier's food safety plan and lot-specific records, demonstrating compliance with applicable regulations, are received and approved by the Executive Vice President/Food Safety Director/QA Director prior to use of the lot. Continued use of the supplier requires receipt and review of an audit report as soon as practical.

Records: Audit results and verification of corrective actions taken by direct suppliers are maintained on file by the Food Safety Director/Manager.

Receiving Procedure for Ingredients Requiring a Supply Chain applied Control

For each shipment received, the receiving clerk 1) verifies the shipment is from an approved supplier and 2) inspects the shipment to verify the product received is covered by the supplier approval. If not, the shipment is not accepted until approved by the Food Safety/QA Director or Manager and Procurement, or Plant Manager.

Approved Suppliers for Ingredients Requiring a Supply Chain applied Control

Food Safety Program 21.0.1
Approved Packaging Supplier Procedure 6.10
Approved Raw Material Supplier Procedure 6.2
Vendor Contingency Plan (non leafy greens) 1.2.1
Vendor Leafy Green Contingency Plan 1.20
Approved Supplier List

Sanitation Preventive Controls

SSOP Manual

Equipment Cleaning SSOP's
General Cleaning SSOP's

Preoperational inspection program

APC Testing Program 21.11.1
ATP Testing Program 21.7.1
Daily Pre-Op Sanitation Report

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Recall Plan

Recall Plan

Product Incident (Mock/Withdrawl/Trace/Recall) 4.5

Revision Log

Date	Revision	Changes	Justification	Revisor/Author
7/29/2016	New	New	FSMA requirement	Diana Simpson
1/21/2018	1	Update FS Plan Team members	Change management	Wayne Bailey
2/14/2018	2	Update FS Plan Team members, add temperature controls at key process steps	Change management and additional plan details	Wayne Bailey

Senior Most Company Official Approval

Revision Date	Revison	Senior Approver	Signature
7/29/2016	New	Carter McEntire	See 2016 sign-off in 2016 Manual
1/21/2018	1	Carter McEntire	
2/14/2018	2	Carter McEntire	

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Food Safety Plan for Repacked Produce Items

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Company Overview

This year-round fresh-cut processing and repacking facility was built in 2007. The facility is 163,000 sq.ft and has an average of 600 employees. A variety of fresh cut vegetable products are processed or repacked to meet customer requirements and specifications. The majority of fresh cut product is processed for food service customers, and a smaller portion is for retail sales. Some of the retail product is processed under a co-packing agreement, in which the product and the equipment is owned by New Star Corporation, based in California. Product is produce up to 6 days a week, with one to two production shift and a daily sanitation shift. All ingredients and materials are sourced from approved suppliers.

Food Safety Team

NAME	POSITION
Carter McEntire	CEO / President
Tom Lovelace*	Executive Vice President
Dave Morris	Sr. Vice President, Operations
Kim Pham*	Quality Assurance Director
Daniel Aderhold	Quality Engineer Manager
Waunda Wright	Quality Assurance Supervisor
Wayne Bailey*	Food Safety Director
OPEN	Food Safety Manager
Stephanie Blazer	Food Safety Supervisor
Eric Moulton	Director of Facilities
Luis Ramirez	Maintenance Director
Bobby Coggins	Repack Director
Rudy Branham	Processing Director
Mike Sexton	Vice President, Supply Chain

*Preventive Controls Qualified Individual

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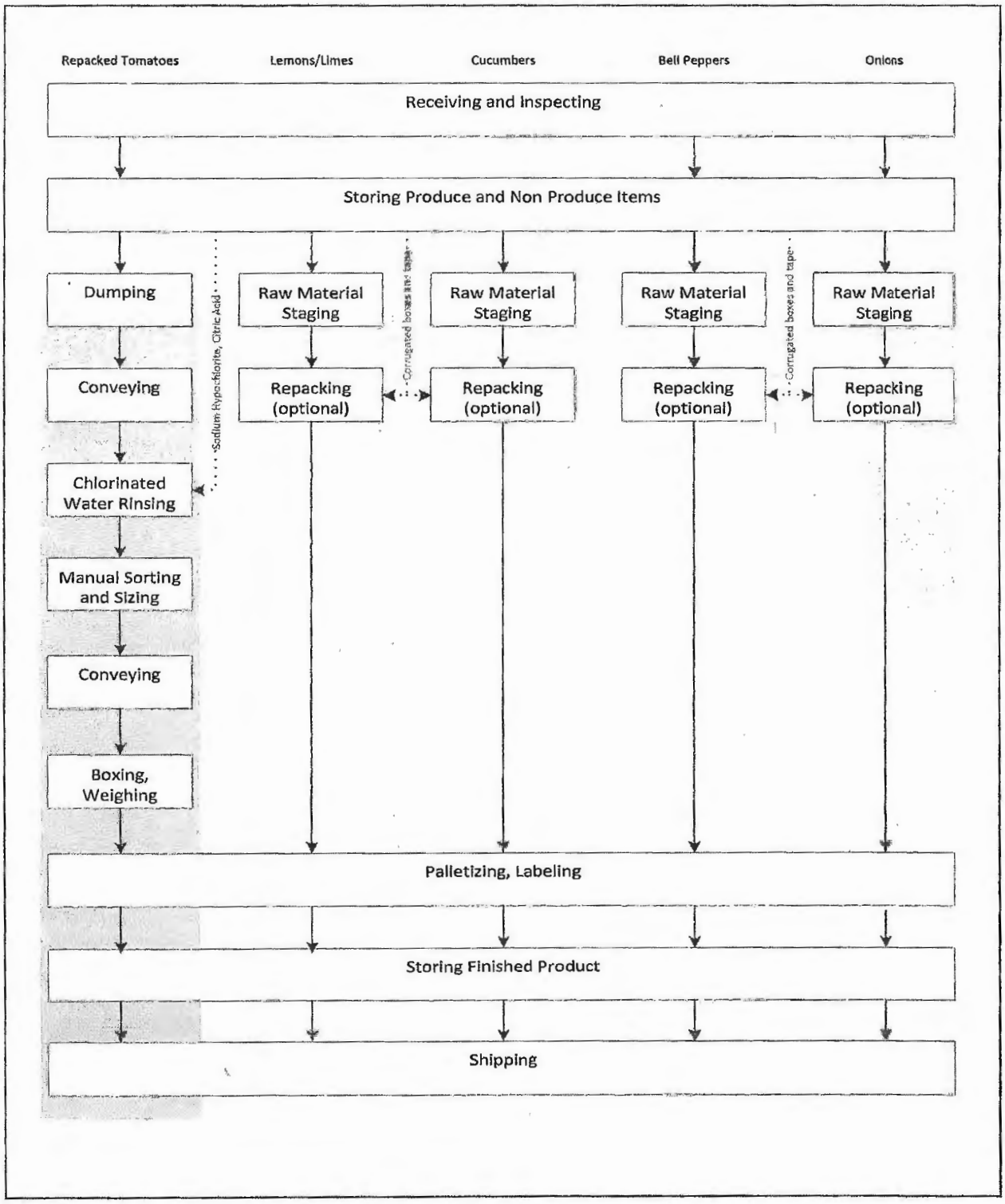
Product Description

Product Name(s):	Whole Repacked Produce Items - Tomatoes, Limes, Lemons, Cucumber, Bell Peppers, Yellow Onions, Red Onions
Product Description, including Important Food Safety Characteristics:	Refrigerated, repacked raw agricultral commodity
Ingredients:	May contain tomatoes, limes, lemons, cucumbers, bell peppers, yellow onions, red onions
Allergens:	None in product
Packaging Used:	Cardboard Boxes
Intended Use:	Intended for for consumption after washing
Intended Customers:	General Public
Shelf Life:	Typically 10 days, or as requested by customer
Labeling Instructions:	Date of Re-Pack
Other Labeling (as applicable):	None
Storage and Distribution:	Refrigerated (34-40°F) storage and distribution

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Flow Diagram



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Process Narrative

Receiving and Inspecting		Bulk raw items are received from approved suppliers and verified at receipt. All grower suppliers are pre-verified compliant with the Produce Safety rule. Produce brokers are required to demonstrate all raw produce is from growers compliant with the Produce Safety rule. Produce is inspected for quality per receiving specifications and accepted or rejected. Non-produce materials such as chemicals, packaging, labels, tape, etc. are received from approved suppliers and inspected on receipt.
Storing Produce and Non Produce Items		Produce is stored in an on-site cooler up to a maximum number of days per commodity specification. Product is used by harvest date (oldest first), except as needed per product/customer specification. Non-produce materials are stored per supplier recommendation and any pertinent regulation.
Repacked Tomatoes		
	Dumping	Boxes of raw tomatoes are manually dumped on to a conveyor.
	Conveying	Product is conveyed and inspected by workers.
	Chlorinated Water Rinsing	Product is conveyed under a spray bar system and rinsed with single pass water containing 1ppm sodium hypochlorite and a buffer solution (citric acid) to keep the pH ≤6.5. The chemicals are injected and monitored continuously via a PLC system with pumps and calibrated probes.
	Manual Sorting and Sizing	Product is conveyed and inspected by workers. Product is culled as needed.
	Conveying	Sorted product is coveyed to corrugated cardboard boxes.
	Boxing, Weighing	The tomatoes are repacked and weighed in the original corrugated cardboard boxes.
Lemon/Limes		
	Raw Material Staging	Boxes containing raw lemons are staged at the repack station.
	Repacking (Optional)	Lemons are repacked into smaller corrugate container per customer specificaiton.
Cucumbers		
	Raw Material Staging	Boxes containing raw cucumbers are staged at the repack station.
	Repacking (Optional)	Cucumbers are repacked into smaller corrugate containers per customer specificaiton.

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Bell Peppers		
	Raw Material Staging	Boxes containing raw bell peppers are staged at the repack station.
	Repacking (Optional)	Bell Peppers are repacked into smaller corrugate containers per customer specificaiton.
Onions		
	Raw Material Staging	Containers containing raw red or yellow onions are staged at the repack station.
	Repacking (Optional)	Onions are repacked into smaller containers per customer specificalton.
Palletizing, Labeling		Product containers are palletized to fulfill customer order and pallet tags are affixed for traceability. Product is labeled per customer specification.
Storing Finished Product		Palletized product is stored in the finished good coolers until shipping.
Shipping		Product is picked manually and re-palletized as needed to meet customer orders. Product is loaded onto company owned or 3rd party pre-cooled trucks.

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Hazard Analysis

The potential food safety hazards identified 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, including potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

(1) Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Is a preventive control required for potential hazard? Yes	(3) No	(4) Justification for decision in column 3	(5) What preventive control measure(s) can significantly minimize or prevent the hazard?	(6) Is the preventive control applied at this step? Yes	(6) No
Receiving and Inspecting (Produce Items)	B	Salmonella, L. monocytogenes, EHEC, pathogenic viruses and parasites	X		Fresh produce has been linked to foodborne illness due to human and environmental pathogens	Supply-chain Control	X	
	C	Pesticide, agricultural chemicals	X		Pesticides and chemicals unlikely for items sourced domestically, but potential exist in imported produce	Supply-chain Control for imported produce	X	
		Allergens		X	No allergens in products			
	P	Hard, shop objects or choking hazards		X	Subsequent inspection and sorting make this unlikely			
Receiving and	B	None						

Inspecting (Non-produce Items)	C	Wrong chemical or packaging		X	All chemicals and food-contact packaging is approved for use and all non-produce materials are sourced from approved suppliers.			
	P	None						
Storing (Produce Items)	B	Cross-contamination		X	GMP's make hazards during storage unlikely to occur. Items stored covered and physical hazards unlikely to pass subsequent inspections and sorting.			
	C	Sanitation Chemicals		X				
	P	Wood and other debris from damaged pallets, bins and totes.		X				
Storing (Non-produce Items)	B	None		X	GMP's make hazards during storage unlikely to occur. Items stored covered and physical hazards unlikely to pass subsequent inspections and sorting.			
	C	Contamination with hazardous chemicals		X				
	P	Wood and other debris from damaged pallets, bins and totes.		X				
Repacked Tomatoes **Dumping**	B	Pathogens from human contact		X	Unlikely with GMPs			
	C	None						
	P	Foreign materials from boxes		X	Subsequent inspection and sorting make this unlikely			
Repacked Tomatotes **Conveying**	B	Environmental pathogens (L. monocytogenes)	X		Enhanced attention to sanitation warranted	Master sanitation program (SSOPs) and Preoperational inspection program	X	
		Pathogens from human contact		X	Unlikely with GMPs			
	C	None						

	P	None						
Repacked Tomatoes **Chlorinated Water Rinsing**	B	Pathogen cross-contamination		X	Single pass shower makes this an unlikely source of pathogens or cross contamination			
	C	None						
	P	None						
Repacked Tomatoes **Manual Sorting and Sizing**	B	Environmental pathogens (L. monocytogenes)	X		Enhanced attention to sanitation warranted	Master sanitation program (SSOPs) and Preoperational inspection program	X	
		Pathogens from human contact		X	Unlikely with GMPs			
	C	None						
	P	None						
Repacked Tomatoes **Conveying**	B	Environmental pathogens (L. monocytogenes)	X		Enhanced attention to sanitation warranted	Master sanitation program (SSOPs) and Preoperational inspection program	X	
		Pathogens from human contact		X	Unlikely with GMPs			
	C	None						
Repacked Tomatoes **Boxing, Weighing**	B	Pathogens from human contact		X	Unlikely with GMPs			
	C	None						
	P	None						
Lemons/ Limes- **Raw Material Staging**	B	Cross-contamination		X	GMP's make hazards during storage unlikely to occur.			
	C	None						
	P	Wood and other debris from damaged pallets, bins and totes.		X	Items transported covered and physical hazards unlikely to pass subsequent inspections and sorting			

Lemon Wedges - **Packing (optional)**	B	Pathogens from human contact		X	Unlikely with GMPs			
	C	None						
	P	None						
Cucumbers - **Raw Material Staging**	B	Cross-contamination		X	GMP's make hazards during storage unlikely to occur.			
	C	None						
	P	Wood and other debris from damaged pallets, bins and totes.		X	Items transported covered and physical hazards unlikely to pass subsequent inspections and sorting			
Cucumbers - **Packing (optional)**	B	Pathogens from human contact		X	Unlikely with GMPs			
	C	None						
	P	None						
Bell Peppers - **Raw Material Staging**	B	Cross-contamination		X	GMP's make hazards during storage unlikely to occur.			
	C	None						
	P	Wood and other debris from damaged pallets, bins and totes.		X	Items transported covered and physical hazards unlikely to pass subsequent inspections and sorting			
Bell Peppers - **Packing (optional)**	B	Pathogens from human contact		X	Unlikely with GMPs			
	C	None						
	P	None						
Onions - **Raw Material**	B	Cross-contamination		X	GMP's make hazards during storage unlikely to occur.			

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Staging	C	None						
	P	Wood and other debris from damaged pallets, bins and totes.		X	Items transported covered and physical hazards unlikely to pass subsequent inspections and sorting			
Onions -	B	Pathogens from		X	Unlikely with GMPs			
	C	None						
Packing (optional)	P	None						
Palletizing, Labeling	B	None						
	C	None						
	P	None						
Storing in inventory	B	Pathogen growth if temperature abused		X	Significant temperature abuse unlikely to go unnoticed			
	C	None						
	P	None						
Shipping	B	Pathogen growth if temperature abused		X	Significant temperature abuse unlikely to go unnoticed			
	C	None						
	P	None						

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Process Preventive Controls

None

Supply Chain Preventive Controls Program

Hazards requiring a supply-chain applied control: Hazard analysis determined that human pathogens, such as Salmonella and STEC E.coli, are significant hazards for raw produce. There is a foreseeable risk of misuse of harmful agricultural chemicals, such as pesticides, in imported produce. These hazards are best controlled at the grower level.

Preventive controls applied by the supplier: Compliance by the grower with the Produce Safety rule minimizes the risk of contamination with human pathogens. Compliance with Good Agricultural Practices and U.S. MRLs minimizes the risk of contamination with harmful agricultural chemicals in imported produce.

Verification activities: McEntire Produce, or a 2nd/3rd party audit growers who supply our produce, by a qualified auditor, is used to verify compliance with the Produce Safety rule. Letters of guarantee are required from suppliers of prewashed onions and carrots that 1) they are in compliance with the Preventive Controls for Human Food rule, 2) they require their fresh produce suppliers to be in compliance with the Produce safety rule; and 3) they require importers of fresh produce to be in compliance with the Foreign Supplier Verification Program rule, including adequate control of the use of potentially harmful agricultural chemicals.

Verification procedures: A copy of a 3rd party audit is requested from all direct suppliers on an annual basis. When produce is supplied through an intermediate (broker or importer), the intermediate must provide a copy of a current 2nd or 3rd party audit report of the supplier, preformed by a qualified auditor. The audit results are reviewed and follow up discussion with the supplier or the intermediate takes place as necessary, to verify that any corrective actions mentioned in the report have been completed.

Records: Audit results and verification of corrective actions taken by direct suppliers are maintained on file by the Food Safety Director/Manager.

Receiving Procedure for Ingredients Requiring a Supply Chain applied Control

For each shipment received, the receiving clerk 1) verifies the shipment is from an approved supplier and 2) inspects the shipment to verify the product received is covered by the supplier approval. If not, the shipment is not accepted until approved by the Food Safety/QA Director or Manager and Procurement, or Plant Manager.

Approved Suppliers for Ingredients Requiring a Supply Chain applied Control

Food Safety Program 21.0.1
Approved Packaging Supplier Procedure 6.10
Approved Raw Material Supplier Procedure 6.2
Vendor Contingency Plan (non leafy greens) 1.2.1
Vendor Leafy Green Contingency Plan 1.20
Approved Supplier List

McEntire Produce
2040 American Italian Way
Columbia, SC 29209
Repacked Produce Items

ISSUE DATE: 2/14/2018
SUPERSEDES: 7/29/2016

Sanitation Preventive Controls

SSOP Manual

Equipment Cleaning SSOP's
General Cleaning SSOP's

Preoperational inspection program

APC Testing Program 21.11.1
ATP Testing Program 21.7.1
Daily Pre-Op Sanitation Report

McEntire Produce
2040 American Italian Way
Columbia, SC 29209
Repacked Produce Items

ISSUE DATE: 2/14/2018
SUPERSEDES: 7/29/2016

Recall Plan

Recall Plan

Product Incident (Mock/Withdrawl/Trace/Recall) 4.5

Revision Log

Date	Revision	Changes	Justification	Revisor/Author
7/29/2016	New	New	FSMA requirement	Diana Simpson
2/14/2018	1	Update FS Plan Team	Change management	Wayne Bailey

Senior Most Company Official Approval

Revision Date	Revison	Senior Approver	Signature
7/29/2016	New	Carter McEntire	See 2016 sign-off in 2016 Manual
2/14/2018	1	Carter McEntire	

Audit Report

Global Standard for Food Safety Issue 6: July 2011

1.Audit Summary			
Company name	McEntire Produce, Inc.	BRC Site Code	2100420
Site name	McEntire Produce- Columbia		
Scope of audit	The cutting (slicing, dicing, shredding and slivering) of fresh fruits and vegetables packed into polyethylene bags and clam shells, and the sorting and washing of whole fruits and vegetables packed into corrugated boxes.		
Exclusions from scope	None		
Audit Finish Date	2015-03-12		

2. Results					
Audit result	Certificated	Audit grade	A	Audit type	Announced

Audit frequency	12 months	Re-audit due date	2016-05-09
Present Previous audit grade	A	Previous audit date	2014-04-30

Number of Non-Conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	8

3.Company Details			
Address	2040 American Italian Way, Columbia, South Carolina		
Country	United States	Telephone	803-744-2888
Commercial representative Name	Kim Pham	Email	kim.pham@mcentireproduce.com
Technical representative Name	Kim Pham	Email	kim.pham@mcentireproduce.com

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4.Company Profile

Plant size (metres square)	15,335	No. of employees	630	No. of HACCP plans	11

Subcontracted processes	No
Other certificates held	Organic
Regions exported to	None
Major changes since last BRC audit	.

Company Description

McEntire Produce located in Columbia, South Carolina, a family-owned fresh produce processor in the Southeast. McEntire Produce manufactures fresh cut tomatoes, vegetable and whole repacked tomato products. The 165,000 square foot facility employs a total of 630 workers on three shifts; two production shifts and one sanitation shift. The facility has 11 manufacturing lines and runs 6 days a week. Unloading of two delivery trucks and the loading of product on one shipping truck was observed on the first day of the audit. Pre-op activities were observed at first shift start-up on the second day of the audit. Investment during the last 12 months included the installation of a second fresh water rinse system and a new electronic operations management system called Red Zone. At the time of the audit the facility is in process of installing a new bagging machine for cut product.

5.Product Characteristics

Product categories	06 - Prepared fruit, vegetable and nuts
Finished product safety rationale	The produce is washed in chlorinated water. Temperature are maintained at 33-40 F during processing activities.

High care	Yes	High risk	No

Allergens handled on site	None
Product claims made e.g. IP, organic	Organic

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5.Product Characteristics	
Product recalls in last 12 Months	No
Products in production at the time of the audit	.

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6.Audit Duration Details			
On-site duration	20	Duration of production facility inspection	10
Reasons for deviation from typical or expected audit duration	None		
Next audit type selected	Announced		

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1	2015-03-10	08:00	17:30
2	2015-03-11	06:45	16:45
3	2015-03-12	08:00	09:30

7.Key Personnel			
Auditor Number	233041	Auditor Names and roles	Eva Miklos

Present at audit				
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.9)				
Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Carter McEntire/President & CEO	x			x
Kim Pham /Director of Quality	x	x	x	x
Bob Ziel /Director of Food Safety	x	x	x	x

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Present at audit				
Diana Simpson/Food Safety Manager	x	x	x	x
Dan Aderhold/Eng. Quality Assurance	x	x	x	x
Dave Morris/VP Operations	x			x
Amir Hadziamhmetovic/Project Director	x			x
Bobby Cobbins/Tomato Repack Manager	x			x
Luis Ramirez /Maintenance Manager	x		x	x
Pete Luna/Director of Transportation	x			x
Thomas Galloway/ Human Resources	x			x

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GLOBAL STANDARD FOR FOOD SAFETY

Non-Conformity Summary Sheet

Critical or Major Non Conformities Against Fundamental Requirements				
No.	Requirement ref.	Details of non-conformity	Critical or Major?	Anticipated re-audit date

Critical			
No.	Requirement ref.	Details of non-conformity	Anticipated re-audit date

Major							
No.	Requirement ref.	Details of non-conformity	Corrective action taken	Root cause analysis and proposed action plan	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by

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GLOBAL STANDARD FOR FOOD SAFETY

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Minor							
No.	Requirement ref.	Details of non-conformity	Corrective action taken	Root cause analysis and proposed action plan	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by
1	2.10.1	Monitoring procedures in the HACCP plan for Free Chlorine (CCP1) and Metal Detection (CCP2) describe the frequency checks being completed hourly. The frequency did not include a monitoring check requirement at the beginning of shift, end of the shift and at product change. On the CCP records it was evident that checks were made at the correct frequency (start up, hourly, end of shift and at product change), however, this was not mentioned in the HACCP plan.	HACCP plans have been revised on 3/16/15 to reflect current process for CCP monitoring frequency at start up, hourly, changeover, and at end of shift.	HACCP team reviews HACCP program at a minimum annually. We will make it a focus to ensure the HACCP program is reviewed in details and written to reflect current processes and programs.	HACCP Plans CCPs Frequency	2015/03/30	Eva Miklos
2	3.2.1	During the facility inspection an uncontrolled document (Tomato Line Product Report) was observed to be in use in the tomato packing area.	Tomato Repack personnel was trained on document control guidelines on 3/30/15.Attached the updated Tomato Repack Production Report (controlled document) and training record.	Tomato Repack personnel was not properly trained on document control guidelines.	Training Record & Revised Tomato Repack Daily Production Sheet	2015/03/31	Eva Miklos
3	4.2.1	While inspecting the outside grounds 3 exterior doors (to the production room, to water filtration system and to Admin. stairwell) were found unsecured, against company policy (Security Policies and Procedures 4.11).	Conducted re-training for all operation employees in regards to emergency exit doors on 3/30/15 and 3/31/15. They must be secured and completely closed at all times to prevent unauthorized access to the facility. Emergency	Emergency doors are being used as exit/entrance.	Training Record for Emergency Doors Security	2015/04/03	Eva Miklos

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GLOBAL STANDARD FOR FOOD SAFETY

NSF

Minor							
			exit doors must only be used in the event of an emergency evacuation. In addition, facility maintenance will install and trial an alarm mechanism for one specific emergency door. Once alarm mechanism has been tested, proposal for installation of alarm mechanism will be submitted for other emergency doors.				
4	4.4.5	The insulation cover around the water pipe on cut deck, directly above the produce shaker, was damaged.	Work order or requisition has been submitted on 4/1/15 to have contractor replace pipe insulations on the cutting deck on Sunday 4/5/15 on a non production day. See attached Training Record and Revised GMP's Inspection List.	Daily pre start up inspection did not note issue with damaged pipe cover or insulation.	Work order for pipe insulation repair;Training Record and Revised GMP's Inspection List	2015/04/14	Eva Miklos
5	4.6.1	The translicer chute on Line 6 located on the cut deck was found damaged with open seams.	Equipment was repaired on 3/14/15. Added equipment condition inspection to pre-op inspection list on 4/4/15. See attached Training Record & Revised Pre-op Inspection List.	Pre-op inspection did not identify equipment conditions and initiate work order for repair.	Picture of repaired Translicer Chute;Training Record & Revised Pre-op Inspection List	2015/04/14	Eva Miklos
6	4.7.1	Although a Planned Maintenance schedule existed, the PM work for the Diversacut 2110 slicer has not been documented since 1/6/2015. The Diversacut is scheduled for monthly	Maintenance Supervisors were trained on revised policy Maintenance SOP 5.1. A review is required by the 15th of each	PMs were not reviewed at a defined frequency to make sure the planned schedule was followed.	Training record for preventive maintenance and revised	2015/04/07	Eva Miklos

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Minor							
		planned maintenance in the MP2 system.	month. All work orders will be reviewed for completion.		Maintenance SOP 5.1		
7	5.4.2	Partially used packaging materials were seen stored unprotected on the second floor packaging materials storage. Open boxes with plastic bags and rolls of printed and clear film were found without being properly covered.	Packaging Machine Operators were re-trained on proper protocol for storing of packaging film on 3/28/15 & 3/30/15. Packaging materials were re-wrapped and covered.	2nd floor mezzanine area Supervision did not inspect for daily GMP's compliance.	Training Record for Packaging Storage	2015/03/31	Eva Miklos
8	7.4.1	According to company policy (GMP Guidelines 1.9) employees in low risk areas are required to wear blue smocks. There were 3 employees observed assembling boxes in the second floor boxing area wearing street clothes.	All personnel working in the 2nd floor mezzanine area has been re-trained on GMP's guidelines in regards to outer protective clothing. Training was completed on 3/17 & 3/19/15.	2nd floor mezzanine area Supervisor did not inspect for daily GMP's compliance.	GMP's Training Record for 2nd floor box mezzanine area employees	2015/03/20	Eva Miklos

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GLOBAL STANDARD FOR FOOD SAFETY

Detailed Audit Report

1 SENIOR MANAGEMENT COMMITMENT

The McEntire Produce senior management team is led by Chief Operating Officer, Carter McEntire, and VP of Operations, Dave Morris. The Director of Quality Assurance, Kim Pham, and the Director of Food Safety, Bob Ziel, are responsible for day to day Food Safety and Food Quality systems and they report at senior management team meetings.

The senior management demonstrated commitment to the implementation and maintenance of the Standard requirements. There is a documented food safety policy, which was signed by the VP of Operations on February 13, 2015. The Policy was posted on the main board at the employee entrance to the plant and included within the electronic Quality Manual.

Management objectives have been developed as follows:
-Maintain BRC certification
-Complaints rate - .75% complaints per one thousand case of product sold. YTD - .32%
- Bag seal failure under 5% - YTD 2%
-Pre-op visual inspection – 95% pass - YTD 96%.
-ATP first pass – 97% - YTD 98%.

Progress toward goals is evaluated at the quarterly Executive Meetings and at the monthly Management Meetings. Progress towards attaining KPI success is clearly communicated to employees via posted updates and message boards throughout the facility as well as through the 4DX Program.

In addition Weekly Operations Review Meetings also discuss efficiency and performance data. Weekly plant meetings with all plant employees are conducted through the 4DX Program.
Minutes of two of the monthly meeting (January and February 2015) were reviewed. Items discussed included customer complaints received, bag integrity issues, and results of monthly inspections and internal audits.

An original copy of the BRC Standard, Version 6, was observed during the audit.

Company keeps themselves informed of audit and regulatory standards through the use of the FDA and USDA web site, Codex, newsletters and trade periodicals, as well as by attending training sessions. The site is a member of the United Fresh Association and members of management attend quarterly Food Safety and Technology Council Meetings.

The facility appears to have adequate human and financial resources to comply with all elements of the BRC Standard as evidenced by capital investments in the facility.

The 4 minor NCs that had been raised on the previous audit were reviewed and found to be effectively closed.

The audit due date was also met (due by June 20, 2015); stated on the current certificate.

Requirement No	REQUIREMENT	Conforms
FUNDAMENTAL Statement of Intent	**The company's senior management shall demonstrate they are fully committed to the implementation of the requirements of the Global Standard for Food Safety and to processes which facilitate continual improvement of food safety and quality management.**	Y

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1.1.1	The company shall have a documented policy which states the company's intention to meet its obligation to produce safe and legal products to the specified quality and its responsibility to its customers. This shall be: • signed by the person with overall responsibility for the site • communicated to all staff.	Y
1.1.2	The company's senior management shall ensure that clear objectives are defined to maintain and improve the safety, legality and quality of products manufactured, in accordance with the quality policy and this Standard. These objectives shall be: • documented and include targets or clear measures of success • clearly communicated to relevant staff • monitored and results reported at least quarterly to site senior management.	Y
1.1.3	Management review meetings attended by the site's senior management shall be undertaken at appropriate planned intervals, annually as a minimum, to review the site performance against the Standard and objectives set in 1.1.2. The review process shall include the evaluation of: • previous management review action plans and time frames • results of internal, second party and/or third party audits • customer complaints and results of any customer performance reviews • incidents, corrective actions, out of specification results and non-conforming materials • review of the management of the HACCP system • resource requirements. Records of the meeting shall be documented and used to revise the objectives. The decisions and actions agreed within the review process shall be effectively communicated to appropriate staff, and actions implemented within agreed time scale	Y
1.1.4	The company shall have a demonstrable meeting programme which enables food safety, legality and quality issues to be brought to the attention of senior management at least monthly and allows for the resolution of issues requiring immediate action	Y
1.1.5	The company's senior management shall provide the human and financial resources required to produce food safely in compliance with the requirements of this Standard and for the implementation of the HACCP-based food safety plan.	Y
1.1.6	The company's senior management shall have a system in place to ensure that the company is kept informed of scientific and technical developments, industry codes of practice and all relevant legislation applicable in the country of raw material supply, production and, where known, the country where the product will be sold.	Y

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1.1.7		The company shall have a genuine, original hard copy or electronic version of the current Standard available.	Y
1.1.8		Where the company is certificated to the Standard it shall ensure that announced recertification audits occur on or before the audit due date indicated on the certificate.	Y
1.1.9		The Most senior production or operation manager on site shall attend the opening and closing meetings of the audit for Global Standard for Food Safety certification. Relevant departmental managers or their deputies shall be available as required during the audit.	Y
1.1.10		The company's senior management shall ensure that the root causes of non-conformities identified at the prvious audit against the Standard have been effectively addressed to prevent recurrence.	Y
1.2	**Organisational structure, responsibilities and management authority**		

An experienced management team was in place, including the CEO, VP of Operations, Quality Assurance Director, Food Safety Director, Project Director, Tomato Repack Manager, and Maintenance Manager.

The organizational chart that defined the personnel reporting structure was reviewed. Detailed job descriptions were in place for all key employees (example QA Manager, Food Safety manager and Maintenance Manager). The organizational chart was dated March 9,2014.

Deputizing responsibilities and arrangements were documented. Work instructions and operating procedures were in place these were held electronically, and were available via the Company intranet system. Employee job responsibilities are communicated in various ways such as detailed job descriptions, and through training.

Statement of Intent	**The company shall have a clear organisational structure and lines of communication to enable effective management of product safety, legality and quality.**	**Y**
1.2.1	The company shall have an organisation chart demonstrating the management structure of the company. The responsibilities for the management of activities which ensure food safety, legality and quality shall be clearly allocated and understood by the managers responsible. It shall be clearly documented who deputises in the absence of the responsible person.	Y
1.2.2	The company's senior management shall ensure that all employees are aware of their responsibilities. Where documented work instructions exist for activities undertaken, the relevant employees shall have access to these and be able to demonstrate that work is carried out in accordance with the instruction.	Y
2	**THE FOOD SAFETY PLAN – HACCP**	

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Kim Pham – Quality Assurance Director, led the multi-disciplinary HACCP Team. The Team included the Food Safety Director, VP of Operations and representatives from Technical, Production, and Maintenance departments. The QA Director holds a HACCP certificate dated May 21-23, 2002 from the University of Georgia. The Food Safety Manager has a HACCP Certification dated 6/12/10. The other members of the team have been trained internally on Feb.23-28, 2014, with all team members having extensive food industry experience. All new employees are trained on HACCP as part of their orientation with annual employee refresher training including a HACCP review and update.

The Product description has all the requirements of the standard and includes the intended use by the general population and storage and transportation requirements under controlled temperatures between 33-60F depending on the product. Most products were packaged in plastic bags or heal sealed trays. Repacked tomatoes were packaged into corrugated boxes.

Product shelf life was documented as 10 day shelf life or as requested by the customer.

The hazard analysis was conducted with knowledge of relevant information regarding these products from experience, scientific literature, recognized standards of the industry, customer requirements, etc.

The HACCP Plan is fully developed, implemented and demonstrates on-going effectiveness.

There are 11 HACCP Plans for all products produced at this location: HACCP Lines 4,5 and 6. HACCP RTE (Grape Tomato), HACCP Tender Leaf, HACCP Whole Tomato, HACCP Plan Cucumber and Diced Celery, HACCP Plan Onion Ring, HACCP Plan Diced Tomato and Pico De Gallo, HACCP Plan Simply Clean Lines 3 and 7, HACCP Plan Sliced Tomato, HACCP Plan Lemon Wedges and HACCP Plan WIP Peeled Onion.

The HACCP team has identified wash water chlorine levels and metal detection as critical control points.
CCP1A: Insanitary Wash Water, (STEC, Shigella, Salmonella, L. monoytogenes).
CCP1B is the same as 1A, with the Critical Limit (CL)- chlorine level in the wash water at least 1 ppm
CCP2: Metal Detection with Critical Limit (CL) - metal detector sensitivity of 2.0 mm Fe, 3.0 mm NFe and 3.5 mm for Stainless Steel.
CCPs were monitored and checked at start up,
hourly and at end of production, as well as at product change. Only the hourly frequency was described in the HACCP plan, this warranted non-conformity to be raised against clause
2.10.2.

Corrective actions were to be taken when CCP critical limits were exceeded or failed, and were documented on the CCP Deviation Report. Product was placed on hold back to the last acceptable verification and run back through the process at the appropriate step. The product was managed per the handling of Non-Conforming Product procedure.

Records, verification and direct observations are done on computer (Red Zone system) with on time verification. The program is designed to signal missed entries. Records were observed during the tour and the trace exercise.

All metal detectors were provided with push bar rejection mechanism or retract belt.

The most recent HACCP plan review conducted on March 6, 2015 was seen to be satisfactory. The HACCP plans were supported by a comprehensive pre-requisite program, including sanitation, pest control, preventive maintenance, GMPs, personal hygiene, staff training, transportation, allergen control, food defense and site security controls.

The plant schematic shows the premises and equipment layout. The process flow diagram was most recently reviewed on site by the HACCP team on March 6, 2015.

One minor non-conformity was raised in this section.

FUNDAMENTAL Statement of Intent	**The company shall have a fully implemented and effective food safety plan based on Codex Alimentarius HACCP principles.**	Y

2.1 THE HACCP FOOD SAFETY TEAM – CODEX ALIMENTARIUS STEP 1

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FUNDAMENTAL Statement of Intent		**The HACCP plan shall be developed and managed by a multi-disciplinary food safety team that includes those responsible for quality/technical, production operations, engineering and other relevant functions. The team leader shall have an in-depth knowledge of HACCP and be able to demonstrate competence and experience. The team members shall have specific knowledge of HACCP and relevant knowledge of product, process and associated hazards. In the event of the company not having appropriate in-house knowledge, external expertise may be used, but day-to-day management of the food safety system shall remain the responsibility of the company.**	Y
2.2		**Prerequisite programmes**	
2.2.1		The company shall establish and maintain environmental and operational programmes necessary to create an environment suitable to produce safe and legal food products (prerequisite programmes). As a guide these may include the following, although this is not an exhaustive list: • cleaning and sanitising • pest control • maintenance programmes for equipment and buildings • personal hygiene requirements • staff training • purchasing • transportation arrangements • processes to prevent cross-contamination • allergen controls. The control measures and monitoring procedures for the prerequisite programmes must be clearly documented and shall be included within the development and reviews of the HACCP	Y
2.3		**Describe the product – Codex Alimentarius Step 2**	
2.3.1		The scope of each HACCP plan, including the products and processes covered, shall be defined. For each product or group of products a full description shall be developed, which includes all relevant information on food safety. As a guide, this may include the following, although this is not an exhaustive list: • composition, e.g. raw materials, ingredients, allergens, recipe • origin of ingredients • physical or chemical properties that impact food safety, e.g. pH, aw • treatment and processing, e.g. cooking, cooling • packaging system, e.g. modified atmosphere, vacuum • storage and distribution conditions, e.g. chilled, ambient • target safe shelf life under prescribed storage and usage conditions • instructions for use, and potential for known customer misuse, e.g. storage, preparation.	Y

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2.3.2	All relevant information needed to conduct the hazard analysis shall be collected, maintained, documented and updated. The company will ensure that the HACCP plan is based on this may include the following, although this is not an exhaustive list: • the latest scientific literature • historical and known hazards associated with specific food products • relevant codes of practice • recognised guidelines • food safety legislation relevant for the production and sale of products • customer requirements	Y
2.4	**Identify intended use - Codex Alimentarius Step 3**	
2.4.1	The intended use of the product by the customer shall be described, defining the consumer target groups, including the suitability of the product for vulnerable groups of the population (e.g. infants, elderly, and allergy sufferers).	Y
2.5	**Construct a process flow diagram – Codex Alimentarius Step 4**	
2.5.1	A flow diagram shall be prepared to cover each product, product category or process. This shall set out all aspects of the food process operation within the HACCP scope, from raw material receipt through to processing, storage and distribution. As a guide, this should include the following, although this is not an exhaustive list: • plan of premises and equipment layout • raw materials including introduction of utilities and other contact materials, e.g. water, packaging • sequence and interaction of all process steps • outsourced processes and subcontracted work • process parameters • potential for process delay • rework and recycling • low/high-care/high-risk area segregation • finished products, intermediate/semi-processed products, by-products and waste.	Y
2.6	**Verify flow diagram - Codex Alimentarius Step 5**	
2.6.1	The HACCP food safety team shall verify the accuracy of the flow diagrams by on-site audit and challenge at least annually. Daily and seasonal variations shall be considered and evaluated. Records of verified flow diagrams shall be maintained.	Y
2.7	**List all potential hazards associated with each process step, conduct a hazard analysis and consider any measures to con**	

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2.7.1	The HACCP food safety team shall identify and record all the potential hazards that are reasonably expected to occur at each step in relation to product, process and facilities. This shall include hazards present in raw materials, those introduced during the process or surviving the process steps, and allergen risks (refer to clause 5.2). It shall also take account of the preceding and following steps in the process chain.	Y
2.7.2	The HACCP food safety team shall conduct a hazard analysis to identify hazards which need to be prevented, eliminated or reduced to acceptable levels. Consideration shall be given to the following: • likely occurrence of hazard • severity of the effects on consumer safety • vulnerability of those exposed • survival and multiplication of micro-organisms of specific concern to the product • presence or production of toxins, chemicals or foreign bodies • contamination of raw materials, intermediate/semi-processed product, or finished product. Where elimination of the hazard is not practical, justification for acceptable levels of the hazard in the finished product shall be determined and documented.	Y
2.7.3	The HACCP food safety team shall consider the control measures necessary to prevent or eliminate a food safety hazard or reduce it to an acceptable level. Where the control is achieved through existing prerequisite programmes, this shall be stated and the adequacy of the programme to control the hazard validated. Consideration may be given to using more than one control measure.	Y
2.8	**Determine the critical control points (CCP) – Codex Alimentarius Step 7, Principle 2**	
2.8.1	For each hazard that requires control, control points shall be reviewed to identify those that are critical. This requires a logical approach and may be facilitated by use of a decision tree. CCPs shall be those control points which are required in order to prevent or eliminate a food safety hazard or reduce it to an acceptable level. If a hazard is identified at a step where control is necessary for safety but the control does not exist, the product or process shall be	Y
2.9	**Establish critical limits for each CCP – Codex Alimentarius Step 8, Principle 3**	
2.9.1	For each CCP, the appropriate critical limits shall be defined in order to identify clearly whether the process is in or out of control. Critical limits shall be: • measurable wherever possible, e.g. time, temperature, pH • supported by clear guidance or examples where measures are subjective, e.g. photographs	Y

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2.9.2	The HACCP food safety team shall validate each CCP. Documented evidence shall show that the control measures selected and critical limits identified are capable of consistently controlling the hazard to the specified acceptable level.	Y
2.10	**Establish a monitoring system for each CCP – Codex Alimentarius Step 9, Principle 4**	
2.10.1	A monitoring procedure shall be established for each CCP to ensure compliance with critical limits. The monitoring system shall be able to detect loss of control of CCPs and wherever possible provide information in time for corrective action to be taken. As a guide, consideration may be given to the following, although this is not an exhaustive list: • online measurement • offline measurement • continuous measurement, e.g. thermographs, pH meters etc. • where discontinuous measurement is used, the system shall ensure that the sample taken is representative of the batch of product.	N
2.10.2	Records associated with the monitoring of each CCP shall include the date, time and result of measurement and shall be signed by the person responsible for the monitoring and verified, as appropriate, by an authorised person. Where records are in electronic form there shall be evidence that records have been checked and verified.	Y
2.11	**Establish a corrective action plan – Codex Alimentarius Step 10, Principle 5**	
2.11.1	The HACCP food safety team shall specify and document the corrective action to be taken when monitored results indicate a failure to meet a control limit, or when monitored results indicate a trend towards loss of control. This shall include the action to be taken by nominated personnel with regard to any products that have been manufactured during the period when the process was out of control.	Y
2.12	**Establish verification procedures – Codex Alimentarius Step 11, Principle 6**	
2.12.1	Procedures of verification shall be established to confirm that the HACCP plan, including controls managed by prerequisite programmes, are effective. Examples of verification activities include: • internal audits • review of records where acceptable limits have been exceeded • review of complaints by enforcement authorities or customers • review of incidents of product withdrawal or recall. Results of verification shall be recorded and communicated to the HACCP food safety team.	Y

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2.13	**HACCP documentation and record keeping – Codex Alimentarius Step 12, Principle 7**	
2.13.1	Documentation and record keeping shall be sufficient to enable the company to verify that the HACCP controls, including controls managed by prerequisite programmes, are in place and maintained.	Y
2.14	**Review the HACCP plan**	
2.14.1	The HACCP food safety team shall review the HACCP plan and prerequisite programmes at least annually and prior to any changes which may affect product safety. As a guide, these may include the following, although this is not an exhaustive list: • change in raw materials or supplier of raw materials • change in ingredients/recipe • change in processing conditions or equipment • change in packaging, storage or distribution conditions • change in consumer use • emergence of a new risk, for example adulteration of an ingredient • developments in scientific information associated with ingredients, process or product. Appropriate changes resulting from the review shall be incorporated into the HACCP plan and/or	Y

3.1 Food safety and quality management system

The Company's Food Safety and Quality Manual covers the scope of the Global Standard for Food Safety and contains the appropriate policies, procedures and work instructions. The manual is in electronic form and available to all staff through the shared drive. Where necessary, printed copies were made available. The manual was reviewed on 3/11/14 by the Quality Director.

Work instructions have been prepared for each function. Many work instructions (measuring diameter of tomato slices, checking color and checking for defect in produce) were seen during the plant inspections, including work videos (set up of Diversacut, loading of dryers, set up of label machine).

All documents, policies, procedures and work instructions have a unique number and revision date. A list of documents with a change log was included, to describe what changed from the previous version. An example was the Tempo SOP 21.5.1, with reason description of ' Add daily use log' added to the form.

As record keeping, a number of crosschecks were carried out in the audit for processing records, corrective action, storage, control of non-conforming product, shipping and receiving and all were found to be the correct version with the exception of one uncontrolled document (Tomato Line Product Report) seen in the Tomato Packing Room.

The records inspected were all found to be legible, in good condition and retrievable. Records were retained for the current year, plus one for quality and safety.

One minor non-conformity was raised in this section.

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Statement of Intent	**The company's processes and procedures to meet the requirements of this Standard shall be documented to allow consistent application, facilitate training, and support due diligence in the production of a safe product.**	Y
3.1.1	The company's documented procedures, working methods and practices shall be collated in the form of a printed or electronic quality manual.	Y
3.1.2	The food safety and quality manual shall be fully implemented and the manual or relevant components shall be readily available to key staff.	Y
3.1.3	All procedures and work instructions shall be clearly legible, unambiguous, in appropriate languages and sufficiently detailed to enable their correct application by appropriate staff. This shall include the use of photographs, diagrams or other pictorial instructions where written communication alone is not sufficient (e.g. there are issues of literacy or foreign language).	Y
3.2	**Documentation control**	
Statement of Intent	**The company shall operate an effective document control system to ensure that only the correct versions of documents, including recording forms, are available and in use.**	Y
3.2.1	The company shall operate an effective document control system to ensure that only the correct versions of documents, including recording forms, are available and in use.	N
3.3	**Record completion and maintenance**	
Statement of Intent	**The company shall maintain genuine records to demonstrate the effective control of product safety, legality and quality.**	Y
3.3.1	Records shall be legible, retained in good condition and retrievable. Any alterations to records shall be authorised and justification for alteration shall be recorded. Where records are in electronic form these shall be suitably backed up to prevent loss.	Y
3.3.2	Records shall be retained for a defined period with consideration given to any legal or customer requirements and to the shelf life of the product. This shall take into account, where it is specified on the label, the possibility that shelf life may be extended by the consumer (e.g. by freezing). As a minimum, records shall be retained for the shelf life of the product plus 12 months.	Y
3.4	**Internal audit**	

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The company has a planned program for internal audits (8.11.2) as specified in the Food Safety Quality Manual.

Kim Pham, who is appropriately trained, competent and independent of plant processes, conducted the most recent internal audit. This audit, dated July 7, 2014, covered the company requirements as well as the BRC. During the internal audit several non-conformities (9) as well as conformities were noted.

Non-conformities found in all audits are to have a response within 30 days. Completed corrective actions were verified by the QA Director.

In addition to the internal audit GMP/housekeeping inspections are conducted monthly along with a survey of the plant against the Glass/Brittle Plastic list, as well as daily pre-op inspections in all areas.

Observations are assigned for resolution with the responsible manager. Reports for the month of November and December 2014 and January 2015 were reviewed and found to be in good order. The auditor observed pre-op activities on the second day of the audit.

Statement of Intent	**The company shall be able to demonstrate it verifies the effective application of the food safety plan and the implementation of the requirements of the Global Standard for Food Safety.**	**Y**
3.4.1	There shall be a planned programme of internal audits with a scope which covers the implementation of the HACCP programme, prerequisite programmes and procedures implemented to achieve this Standard. The scope and frequency of the audits shall be established in relation to the risks associated with the activity and previous audit performance; all activities shall be covered at least annually.	**Y**
3.4.2	Internal audits shall be carried out by appropriately trained competent auditors, who are independent from the audited department.	**Y**
3.4.3	The internal audit programme shall be fully implemented. Internal audit reports shall identify conformity as well as non-conformity and the results shall be reported to the personnel responsible for the activity audited. Corrective actions and timescales for their implementation shall be agreed and completion of the actions verified.	Y
3.4.4	In addition to the internal audit programme there shall be a programme of documented inspections to ensure that the factory environment and processing equipment is maintained in a suitable condition for food production. These inspections shall include: • hygiene inspections to assess cleaning and housekeeping performance • fabrication inspections to identify risks to the product from the building or equipment The frequency of these inspections shall be based on risk but will be no less than once per month in open product areas.	**Y**

3.5 Supplier and raw material approval and performance monitoring

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All suppliers must be approved by the Company Purchasing Department and entered into the electronic system according to procedure SOP 6.2 dated 3/09/2015. The risk levels are categorized using a risk matrix: 1-5, high to low. Suppliers have to be audited by a third party firm (GAP or GFSI). Certificates of Analysis are required from all suppliers of raw materials and packaging materials at time of shipping.

The raw material risk assessment was included in the HACCP Program. An Approved Supplier List was in place and was followed. No exceptions were made. All produce must meet 100% US #1 grade standards or better.

Vendor approval documents, Certificates of Analysis/Compliance as well as the pertinent third party audits were reviewed for Lettuce received from TKM Bengard Farms, LLC.

Requirements for Lettuce were: must be vacuum cooled to 34°F within 4 hours after harvesting, transported at 34-40°F, bins are required to have a harvest and vacuum cool date and time, and must have negative results for E Coli 0157:H7 and Salmonealla. Certificates of Analysis/Compliance were also reviewed for food contact packaging supplied by Golden Extrusions, Inc and for the processing aid – Smart wash.

All materials are inspected on arrival at the site. All requested documents were readily available. Incoming materials are inspected by a Quality Assurance Technician, COA results are compared to product specifications and a label is placed on the inspected and approved materials. The COA verification is followed by testing the product with samples taken and sent to the quality lab.

Service providers are managed according to documented procedures. Formal agreements were in place for the pest control company, waste removal company and contract laboratory.

Contract for the following suppliers of services were checked during this audit:
- Pest Control – Orkin Pest Control
- Waste Handling – All Waste Services Inc
- Laboratory- IEH Labs

3.5.1	The company shall have an effective supplier approval and monitoring system to ensure that any potential risks from raw materials (including packaging) to the safety, legality and quality of the final product are understood and managed.	Y
3.5.1.1	The company shall undertake a documented risk assessment of each raw material or group of raw materials to identify potential risks to product safety, legality and quality. This shall take into account the potential for: • allergen contamination • foreign body risks • microbiological contamination • chemical contamination. Consideration shall also be given to the significance of a raw material to the quality of the final product. The risk assessment shall form the basis for the raw material acceptance and testing procedure and for the processes adopted for supplier approval and monitoring.	Y

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3.5.1.2	The company shall have a documented supplier approval and ongoing monitoring procedure to ensure that suppliers are manufacturing products under hygienic conditions, effectively manage risks to raw material quality and safety and are operating effective traceability processes. The approval and monitoring procedure shall be based on one or a combination of: • supplier audits • third party audits or certification, e.g. to BRC Global Standards • supplier questionnaires. Where approval is based on questionnaires, these shall be reissued at least every three years and suppliers required to notify the site of any significant changes in the interim.	Y
3.5.1.3	The procedures shall define how exceptions are handled (e.g. where raw material suppliers are prescribed by a customer or where products are purchased from agents and direct audit or monitoring has not been undertaken).	Y
3.5.2	**Raw material and packaging acceptance and monitoring procedures**	
Statement of Intent	**Controls on the acceptance of raw materials shall ensure that raw materials do not compromise the safety, legality or quality of products.**	Y
3.5.2.1	The company shall have a documented procedure for the acceptance of raw materials and packaging on receipt based upon the risk assessment (3.5.1). Raw material acceptance and its release for use shall be based on one or a combination of: • visual inspection on receipt • certificates of conformance – specific to each consignment • certificates of analysis • product sampling and testing. A list of raw materials and the requirements to be met for acceptance shall be available. The parameters for acceptance and frequency of testing shall be clearly defined.	Y
3.5.2.2	The procedures shall be fully implemented and records maintained to demonstrate the basis for acceptance of each batch of raw materials.	Y
3.5.3	**Management of suppliers of services**	
Statement of Intent	**The company shall be able to demonstrate that where services are outsourced, the service is appropriate and any risks presented to food safety have been evaluated to ensure effective controls are in place.**	Y

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3.5.3.1	There shall be a documented procedure for the approval and monitoring of suppliers of services. Such services shall include as appropriate: • pest control • laundry services • contracted cleaning • contracted servicing and maintenance of equipment • transport and distribution • off-site storage of ingredients, packaging or products • laboratory testing • catering services • waste management.	Y
3.5.3.2	Contracts or formal agreements shall exist with the suppliers of services which clearly define service expectations and ensure potential food safety risks associated with the service have been addressed.	Y
3.5.4	**Management of outsourced processing**	
Outsourcing was not carried out.		
Statement of Intent	**Where any intermediate process steps in the manufacture of a product which is included within the scope of certification is subcontracted to a third party or undertaken at another company site, this shall be managed to ensure this does not compromise the safety, legality or quality of the product.**	**N/A**
3.5.4.1	The company shall be able to demonstrate that where part of the production process is outsourced and undertaken off site, this has been declared to the brand owner and, where required, approval granted.	N/A
3.5.4.2	The company shall ensure that subcontractors are approved and monitored by successful completion of either a documented site audit or third-party certification to the BRC Global Standard for Food Safety or other GFSI-recognised Standard (see Glossary).	N/A
3.5.4.3	Any outsourced processing operations shall: • be undertaken in accordance with established contracts which clearly define any processing requirements and product specification • maintain product traceability.	N/A
3.5.4.4	The company shall establish inspection and test procedures for outsourced product on return, including visual, chemical and/or microbiological testing, dependent on risk assessment.	N/A

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3.6	Specifications	

Specifications were held for all raw materials, packaging, and finished products per Specification Policy SOP 8.7.29. All specifications for products are based upon the standard McEntire product specifications.

Specifications for raw materials used in the vertical trace exercise were found to be easily accessible and current.

The specifications reviewed in this audit included:
-Iceberg and Romaine Lettuce- TKM Bengard Farms, LLC
-Chopped Romaine 1.5", item # 30004 – McEntire Produce
- Sandwich Lettuce (Iceberg, pre-cut) - McEntire Produce
- Sliced Tomatoes – McEntire Produce
-Smart Wash (buffer- processing aide) – Smart Wash Solutions
-Clear film item PD 6069– Golden extrusions, Inc

The production sheets identify the same ingredients as are on the finished product specification. Specifications are reviewed whenever a change occurs and three years maximum if no changes are made.

Statement of Intent	**Specifications shall exist for raw materials including packaging, finished products and any product or service which could affect the integrity of the finished product.**	**Y**
3.6.1	Specifications for raw materials and packaging shall be adequate and accurate and ensure compliance with relevant safety and legislative requirements. The specifications shall include defined limits for relevant attributes of the material which may affect the quality or safety of the final products (e.g. chemical, microbiological or physical standards).	Y
3.6.2	Manufacturing instructions and process specifications shall comply with recipes and quality criteria as detailed in agreed customer specifications.	Y
3.6.4	The company shall seek formal agreement of specifications with relevant parties. Where specifications are not formally agreed then the company shall be able to demonstrate that it has taken steps to ensure formal agreement is in place.	**Y**
3.6.5	Specifications shall be reviewed whenever products change (e.g. ingredients, processing method) or at least every three years. The date of review and the approval of any changes shall be recorded.	Y
3.6.3	Specifications shall be available for all finished products. These shall either be in the agreed format of the customer or, in the case of branded products, include key data to meet legal requirements and assist the customer in the safe usage of the product.	Y

3.7	CORRECTIVE ACTION

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Corrective actions are managed with the Share Point Analysis and Reporting system. The system generates emails to personnel responsible for corrective actions, root cause identification and verification. Non-conformities requiring corrective action are tracked and trended and reported to senior management monthly.

A review of corrective actions for 2014 as well as the corrective actions and root cause analysis for non-conformities raised at the previous BRC assessment was conducted. One example was the identification and resolution of the pooling of the water in the raw area; issue identified at the last Internal Audit dated July 2014.

Completion of corrective actions is verified for effectiveness by the QA Director. Due to short shelf life most issues require immediate action.

The handling of the non-conformities, corrective and preventative actions was seen to be satisfactory.

FUNDAMENTAL Statement of Intent	**The company shall be able to demonstrate that they use the information from identified failures in the food safety and quality management system to make necessary corrections and prevent recurrence.**	Y
3.7.1	The company shall have a documented procedure for handling non-conformances identified within the scope of this Standard to include: • clear documentation of the non-conformity • assessment of consequences by a suitably competent and authorised person • identification of the corrective action to address the immediate issue • identification of an appropriate timescale for correction • identification of personnel with appropriate authority responsible for corrective action • verification that the corrective action has been implemented and is effective • identification of the root cause of the non-conformity and implementation of any necessary corrective action.	Y

3.8 Control of non-conforming product

Hold and Release Procedure – 8.12.1, is in place. The nonconforming products are isolated and quarantined; traceability is maintained with coding system.

All products that are placed on hold are entered in the hold database. The hold log that includes finished product and raw materials was reviewed. Items seen on hold in the warehouse were found to agree with the hold log.

A physical inventory of products on hold is performed weekly. Products on hold (romaine lettuce) were observed in the designated Hold Area of the warehouse. Hold and Release or Dispose, 2012/11/06 is used for nonconforming product.

Only QA personnel or designate may remove the tag and only after disposition has been decided.

Statement of Intent	**The company shall ensure that any out-of-specification product is effectively managed to prevent release.**	Y

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3.8.1	There shall be documented procedures for managing non-conforming products which include: • the requirement for staff to identify and report potentially non-conforming product • clear identification of non-conforming product, e.g. direct labelling or the use of IT systems • secure storage to prevent accidental release, e.g. isolation areas • referral to the brand owner where required • defined responsibilities for decision making on the use or disposal of products appropriate to the issue, e.g. destruction, reworking, downgrading to an alternative label or acceptance by concession • records of the decision on the use or disposal of the product • records of destruction where product is destroyed for food safety reasons.	Y

3.9 TRACEABILITY

Raw materials, work in progress, food contact materials, and finished product were clearly identified throughout the operation. Traceability is achieved for raw and packaging materials through the supplier's lot numbers to in-process identifications system.

Each product specification includes a definition of a finished product coding system.

A vertical trace exercise was conducted during the audit for Chopped Romaine 1.5" item 3004 that was processed on 1/13/15 over one shift; 427 cases (4270 Lbs.) were produced. Products were traced via the electronic inventory management system. The finished product information was located within two hours and 100% of the product was recovered.

A mass balance was carried out on the Romaine Lettuce, traced back to TKM Bengard Farms,LLC and also the clear film item PD6069 and the Smart Wash buffer that were traced back to the supplier.

During the trace exercise the receiving inspection documents were reviewed, along with LOGs for packaging materials. The product specifications were reviewed with label examples. The trailer inspection sheets were in order along with the order number, carrier and seal identification. Room/cooler/truck temperatures were furnished and within their specs. Sanitation and maintenance paperwork showed there were no issues.

Two other exercises were also conducted by the site in the previous year; with one each on finished product, ingredient and packing with 100% recoveries.

Rework includes repacking or re-casing finished product, traceability is maintained for repackaged products.

FUNDAMENTAL Statement of Intent	**The company shall be able to trace all raw material product lots (including packaging) from their supplier through all stages of processing and despatch to their customer and vice versa.**	Y
3.9.1	Identification of raw materials, including primary and any other relevant packaging and processing aids, intermediate/semi-processed products, part used materials, finished products and materials pending investigation shall be adequate to ensure traceability.	Y
3.9.2	The company shall test the traceability system across the range of product groups to ensure traceability can be determined from raw material to finished product and vice versa, including quantity check/mass balance. This shall occur at a predetermined frequency and results shall be retained for inspection. The test shall take place at least annually. Full traceability should be achievable within four hours.	Y

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3.9.3		Where rework or any reworking operation is performed, traceability shall be maintained.	Y

3.10 Complaint handling

The Customer Service Procedure address customer complaints. Customer complaints are recorded in the IPC Quality Net database by the customer service department.

Most complaints are for discoloration of lettuce (Romaine or Iceberg). An example of changes made at the plant due to consumer complaints was the increase of OTR (oxygen transfer rate) on the smaller bag sizes.

When a complaint or comment is received by customer service, an electronic record is established. The QA department is notified of the complaint, investigates the issue and adds to the record. Costumer Service responds to the costumer. If investigation uncovers non-conformity, plant programs are instituted for corrective actions. All complaints are investigated and summaries are reviewed in management meetings. Complaints levels are constantly monitored.

Complaint reduction is a plant KPI and all complaints and customer comments are tracked and trended. The target for complaint reduction for 2015 was exceeded. Complaint trending is done to help reduce complaints.

Statement of Intent	**Customer complaints shall be handled effectively and information used to reduce recurring complaint levels.**	Y
3.10.1	All complaints shall be recorded, investigated and the results of the investigation and root cause of the issue recorded where sufficient information is provided. Actions appropriate to the seriousness and frequency of the problems identified shall be carried out promptly and effectively by appropriately trained staff.	Y
3.10.2	Complaint data shall be analysed for significant trends and used to implement on-going improvements to product safety, legality and quality, and to avoid recurrence. This analysis shall be made available to relevant staff.	Y

3.11 Management of incidents, product withdrawal and product recall

There was a documented Product Incident, (Mock/Withdrawal/Trace/Recall) SOP 4.4, which addresses the mock recall and withdrawal activities.

The facility also has a First Alert Situation Team led by Carter McEntire. The First Alert Situation guidelines, dated January 8, 2015 covers issues that could impact food safety, legality or quality, with identification of personnel who are to be involved and their contact information.

The procedure includes accounting for all stock, recovery, storage and disposal. Customer supply could be covered primarily from other companies.

Recall and trace is tested at least twice annually, last tested October 16, 2014. McEntire Produce has not had a withdrawal or recall within the past 12 months.

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In the event of a product recall, the Certification Body issuing the current certificate was to be informed within 24 hours of the decision to issue a recall.		
Statement of Intent	**The company shall have a plan and system in place to effectively manage incidents and enable the effective withdrawal and recall of products should this be required.**	Y
3.11.1	The company shall have documented procedures designed to report and effectively manage incidents and potential emergency situations that impact food safety, legality or quality. This shall include consideration of contingency plans to maintain business continuity. Incidents may include: • disruption to key services such as water, energy, transport, refrigeration processes, staff availability and communications • events such as fire, flood or natural disaster • malicious contamination or sabotage. Where products which have been released from the site may be affected by an incident, consideration shall be given to the need to withdraw or recall products.	Y
3.11.2	The company shall have a documented product withdrawal and recall procedure. This shall include as a minimum: • identification of key personnel constituting the recall management team, with clearly identified responsibilities • guidelines for deciding whether a product needs to be recalled or withdrawn and the records to be maintained • an up-to-date list of key contacts or reference to the location of such a list, e.g. recall management team, emergency services, suppliers, customers, Certification Body, regulatory authority • a communication plan including the provision of information to customers, consumers and regulatory authorities in a timely manner • details of external agencies providing advice and support as necessary, e.g. specialist laboratories, regulatory authority and legal expertise • a plan to handle the logistics of product traceability, recovery or disposal of affected product and stock reconciliation. The procedure shall be capable of being operated at any time.	Y
3.11.3	The product recall and withdrawal procedures shall be tested, at least annually, in a way that ensures their effective operation. Results of the test shall be retained and shall include timings of key activities. The results of the test and of any actual recall shall be used to review the procedure and implement improvements as necessary.	Y

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3.11.4	In the event of a product recall, the Certification Body issuing the current certificate for the site against this Standard shall be informed within three working days of the decision to issue a recall.	Y

4 Site Standards

The McEntire Produce facility sits in a large Industrial Park area approximately a mile from the edge of the community of Columbia, South Carolina. The facility was built in 2007 for the purpose of produce processing.

The company complex consists of multiple acres and the facility is completely fenced with security guard at the front gate for visitors and trucks.

Employees enter through a turnstile after scanning their badge to the electronic bar code scanner.

The street in front to of the facility is hard surfaced. A large pasta plant is the closest neighboring plant.

The other two sides are tree lined and secluded.

An inspection of the grounds was completed during the audit. Outside surfaces were paved and observed to be in well maintained and in good condition; drainage of the transportation and parking lots is satisfactory. Housekeeping was adequate in all areas. The building fabric was observed to be in good condition.

GMP audits and planned maintenance inspections monitored the building.

There were no local activities which could have an adverse affect on finished product integrity. The area was suitable for the production of safe and legal products.

4.1	The production site shall be of suitable size, location, construction and design to reduce the risk of contamination and facilitate the production of safe and legal finished products.	Y
4.1.1	Consideration shall be given to local activities and the site environment, which may have an adverse impact on finished product integrity, and measures shall be taken to prevent contamination. Where measures have been put into place to protect the site (from potential contaminants, flooding etc.), they shall be reviewed in response to any changes.	Y
4.1.2	The external areas shall be maintained in good order. Where buildings are surrounded by grassed or planted areas, they shall be regularly tended and well-maintained. External traffic routes under site control shall be suitably surfaced and maintained in good repair to avoid contamination of the product.	Y
4.1.3	The building fabric shall be maintained to minimise potential for product contamination (e.g. elimination of bird roosting sites, sealing gaps around pipes to prevent pest entry, ingress of water and other contaminants).	Y

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4.2	Security	

A security risk assessment had been documented and reviewed by management as part of its annual assessment and found to be adequate. The Food Defense and Facility Security Program version 7, dated 4/22/14 was reviewed. All employees have access keys cards to gain access to the premise at specific times depending on the shift the employee is working.

There is a visitor and contractor reporting procedure. Visitors signed in at the guard house and given a visitor badge for identification.

The entire facility was fenced and gated and was monitored on CCTV. Exterior doors were in good repair, well sealed, and found to be securely locked from the outside, with the exception of 3 doors (production room door, filtration system room door, and stairwell to Admin door).

Trucks are properly sealed against the plant during receiving and shipping activities.

Orientation and annual refresher training of all employees include site security requirements and expected practices.

This site is registered with the South Carolina Department of Agriculture, and with the FDA Bio-terrorism program – last 4 digits 7548.

One minor non-conformity was raised in this section.

Statement of Intent	**Security systems shall ensure that products are protected from theft or malicious contamination whilst under the control of the site.**	Y
4.2.1	The company shall undertake a documented assessment of the security arrangements and potential risks to the products from any deliberate attempt to inflict contamination or damage. Areas shall be assessed according to risk; sensitive or restricted areas shall be defined, clearly marked, monitored and controlled. Identified security arrangements shall be implemented and reviewed at least annually.	N
4.2.2	Measures shall be in place to ensure only authorised personnel have access to production and storage areas and access to the site by employees, contractors and visitors shall be controlled. A visitor reporting system shall be in place. Staff shall be trained in site security procedures and encouraged to report unidentified or unknown visitors.	Y
4.2.3	Where required by legislation, the site shall be registered with, or be approved by, the appropriate authority.	Y

4.3	LAYOUT, PRODUCT FLOW AND SEGREGATION

A detailed site plan of the plant shows the general placement of processing equipment. All contractors and visitors report to Reception and are made aware of site security and hygiene requirements.

The risk of cross contamination has been considered. Effective physical separation is in place between production areas. Separate rooms are in place for reception, processing, packing and storage.

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Specified materials are stored and handled separately. Training, labeling and separate storage areas are used as control measures. A positive airflow has been established in the plant.

Document control, HACCP, hazard analysis and facility maps were reviewed during the audit. The plant has low risk areas and a high care department. The RTE area is separate from the raw area. The site has developed a map that shows all access points for the employees' process flow and the High Care area.

Sufficient working space and storage capacity were present around the lines.

4.3.6 is N/A due to there being no high risk areas present.
4.3.8 is N/A due to there being no temporary structures present.

FUNDAMENTAL Statement of Intent	**The factory layout, flow of processes and movement of personnel shall be sufficient to prevent the risk of product contamination and to comply with relevant legislation.**	Y
4.3.1	There shall be a plan of the site which designates areas where product is at different levels of risk from contamination; that is: • enclosed product areas • low-risk areas • high-care areas • high-risk areas. See Appendix 2 for guidance. This shall be taken into account when determining the prerequisite programmes for the particular areas of the site.	Y
4.3.2	The site plan shall define: • access points for personnel and travel routes • location of staff facilities and routes to the facilities from places of work • production process flow • routes for the removal of waste • routes for the movement of rework. If it is necessary to allow access through production areas, designated walkways shall be provided that ensure there is adequate segregation from materials. All facilities shall be designed and positioned, where possible, so that movement of personnel is by simple, logical routes. The movement of waste and rework shall not compromise the safety of products.	Y
4.3.3	Contractors and visitors, including drivers, shall be made aware of all procedures for access to premises and the requirements of the areas they are visiting, with special reference to hazards and potential product contamination. Contractors involved in maintenance or repair activities shall be under the supervision of a nominated person.	Y

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4.3.4	In low-risk areas the process flow together with the use of demonstrably effective procedures shall be in place to minimise the risk of the contamination of raw materials, intermediate/semi-processed products, packaging and finished products.	Y
4.3.5	Where high-care areas are part of the manufacturing site there should be physical segregation between these areas and other parts of the site. Segregation shall take into account the flow of product, nature of materials, equipment, personnel, waste, airflow, air quality and utilities provision. Where physical barriers are not in place, the site shall have undertaken a full evaluation of the risks of cross-contamination and alternative effective processes shall be in place to protect products from contamination.	Y
4.3.6	Where high-risk areas are part of the manufacturing site, there shall be physical segregation between these areas and other parts of the site. Segregation shall take into account the flow of product, nature of materials, equipment, personnel, waste, airflow, air quality and utilities provision. The location of transfer points shall not compromise the segregation between high-risk areas and other areas of the factory. Practices shall be in place to minimise risk of product contamination (e.g. the disinfection of materials on entry).	N/A
4.3.7	Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out properly under safe hygienic conditions.	Y
4.3.8	Temporary structures constructed during building work or refurbishment, etc. shall be designed and located to avoid pest harbourage and ensure the safety and quality of products.	N/A

4.4 Building fabric Raw material handling, preparation, processing, packing and storage areas

The facility was built (2007) for its' intended purpose and appeared maintained. The building fabric was seen to be generally well maintained. The walls and ceilings are concrete or sanitary FPR panels.

There is a suspended ceilings in the facility with pest control in place and monitored.

The floors are sealed concrete. During pre-op it was observed sanitation drainage was sufficient to remove the high volume of water used to flush the system.

Internal and external doors were well maintained and made of appropriate materials.

Dock loading lights are fitted with shatterproof bulbs. The lighting in the facility is sufficient for operations and all fixtures were fitted with shatterproof coverings. Eight ILT units are in use at the facility. They are located and maintained by the third-party PCO and do not appear to pose a contamination risk.

There are no windows in the process areas. Ventilation systems are adequate and excessive dust / condensation was not observed during this assessment.

4.4.13 is N/A due to there being no high risk areas.

One minor non-conformity was raised in this section.

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Statement of Intent	**The fabrication of the site, buildings and facilities shall be suitable for the intended purpose.**	**Y**
4.4.1	Walls shall be constructed, finished and maintained to prevent the accumulation of dirt, minimise condensation and mould growth, and facilitate cleaning.	**Y**
4.4.2	Floors shall be suitably hard wearing to meet the demands of the process, and withstand cleaning materials and methods. They shall be impervious and maintained in good repair.	Y
4.4.3	Drainage, where provided, shall be sited, designed and maintained to minimise risk of product contamination and not compromise product safety. Machinery and piping shall be arranged so that, wherever feasible, process waste water goes directly to drain. Where significant amounts of water are used, or direct piping to drain is not feasible, floors shall have adequate falls to cope with the flow of any water or effluent towards suitable drainage.	Y
4.4.4	Where sites include high-care or high-risk facilities, there shall be a plan of the drains for these areas which shows the direction of flow and location of any equipment fitted to prevent the back up of waste water. The flow of drains shall not present a risk of contamination of the high-care/risk area.	Y
4.4.5	Ceilings and overheads shall be constructed, finished and maintained to prevent the risk of product contamination.	N
4.4.6	Where suspended ceilings or roof voids are present, adequate access to the void shall be provided to facilitate inspection for pest activity, unless the void is fully sealed.	Y
4.4.7	Where there is a risk to product, windows, and roof glazing which is designed to be opened for ventilation purposes, shall be adequately screened to prevent the ingress of pests.	Y
4.4.8	Where they pose a risk to product, glass windows shall be protected against breakage.	Y
4.4.9	Doors shall be maintained in good condition. External doors and dock levellers shall be close fitting or adequately proofed. External doors to open product areas shall not be opened during production periods except in emergencies. Where external doors to enclosed product areas are opened, suitable precautions shall be taken to prevent pest ingress.	Y
4.4.10	Suitable and sufficient lighting shall be provided for correct operation of processes, inspection of product and effective cleaning.	Y

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4.4.11	Where they constitute a risk to product, bulbs and strip lights – including those on electric fly-killer devices – shall be adequately protected. Where full protection cannot be provided, alternative management such as wire mesh screens or monitoring procedures shall be in place.	Y
4.4.12	Adequate ventilation and extraction shall be provided in product storage and processing environments to prevent condensation or excessive dust.	Y
4.4.13	High-risk areas shall be supplied with sufficient changes of filtered air. The filter specification used and frequency of air changes shall be documented. This shall be based on a risk assessment, taking into account the source of the air and the requirement to maintain a positive air pressure relative to the surrounding areas.	N/A

4.5 Utilities – water, ice, air and other gases

Water used within the operation was potable and drawn from the City of Columbia and from the on-site well. The Water Analysis Testing procedure 8.13.2 version 5 was reviewed.

The annual water certificate of analysis supplied by the city for 2014 is held.

Well Water was tested by a third party laboratory quarterly for microbiological quality, along with an annual test for hard metals. In addition to this the water is tested at the point of use (composite- 5 points) for Coliform and HPC quarterly.

Reviewed lab results sent to Shealy Environmental Laboratories on 3/4/2015. The test was satisfactory. All water inside the plant is potable.

The plant maintains a map of the water system and holding tanks inside the facility.

Compressed air used on product contact surfaces is filtered to 0.5 micron.

No evidence of excessive condensation was observed.

4.5.3 is N/A as there is no non potable water used.

Statement of Intent	**Utilities used within the production and storage areas shall be monitored to effectively control the risk of product contamination.**	Y
4.5.1	All water used as a raw material in the manufacture of processed food, the preparation of product, or for equipment or plant cleaning shall be supplied in sufficient quantity, be potable at point of use or pose no risk of contamination according to applicable legislation. The microbiological and chemical quality of water shall be analysed at least annually. The sampling points and frequency of analysis shall be based on risk, taking into account the source of the water, on-site storage and distribution facilities, previous sample history and usage.	Y

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4.5.2	An up-to-date plan shall be available of the water distribution system on site, including holding tanks, water treatment and water recycling as appropriate. The plan shall be used as a basis for water sampling and the management of water quality.	Y
4.5.3	Where legislation specifically permits the use of water which may not be potable for initial product cleaning (e.g. for the storage/washing of fish), the water shall meet the designated legal requirement for this operation.	N/A
4.5.4	Air, other gases and steam used directly in contact with or as an ingredient in products shall be monitored to ensure this does not represent a contamination risk. Compressed air used directly in contact with the product shall be filtered.	Y

4.6 Equipment

Equipment is suitable for the intended purpose and to minimize the risk of product contamination.

An example of equipment used includes: 6 translicers, 6 dicers, 8 water chillers, 7 packaging machines, 23 produce dryers, 9 bagging scales and various transfer belts.

Certificates of Conformance (or similar evidence) that a material is suitable for food contact use are maintained.

Data sheets for equipment/parts were held in a file and checked for the following:
-Carrot incline belt (Heinz Manufacturing International)
-Translicer on Line 3 (Urschel)

One minor non-conformity was raised in this section

Statement of Intent	**All food processing equipment shall be suitable for the intended purpose and shall be used to minimise the risk of contamination of product.**	Y
4.6.1	All equipment shall be constructed of appropriate materials. The design and placement of equipment shall ensure it can be effectively cleaned and maintained.	N
4.6.2	Equipment which is in direct contact with food shall be suitable for food contact and meet legal requirements where applicable.	Y

4.7 Maintenance

The Company's preventive maintenance plan was based on the equipment manufacturer's recommendations and past experience, and was set in the MP2 computer system. Work orders are generated by the system and can be tracked and trended. Work order requests for non PM work can be generated by supervisors then entered into the MP2 system by maintenance personnel.

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Work orders when complete require a sign-off by maintenance manager and QA prior to reusing the equipment. Documented hygiene procedures are in place to ensure that tools, equipment, and maintenance materials are removed from the production line and that it is sanitary and ready for production.

The maintenance plan for the automatic weighing machines (bagger scales) and Diversacut 2110 slicer was checked. The PM work for the Diversacut has not been documented since 1/6/2015. The Diversa cut is scheduled for monthly planned maintenance in the MP2 system.

Temporary repair concerns are explained in the Adverse Event, (Roof Leak, Drain Back Up, etc, 2014/04/21) procedure. Temporary repairs are not permitted except with the review and approval of the Maintenance Manager.

Lubricants were seen to be appropriately stored; there was no intermingling of food grade products with any other chemicals observed. Technical data and MSDS sheets were verified for :
-Clear insulating varnish EL-600- Sprayon
- Food grade oil

The Maintenance Shop was organized and clean.

One minor non-conformity was raised in this section

Statement of Intent	**An effective maintenance programme shall be in operation for plant and equipment to prevent contamination and reduce the potential for breakdowns.**	Y
4.7.1	There shall be a documented planned maintenance schedule or condition monitoring system which includes all plant and processing equipment. The maintenance requirements shall be defined when commissioning new equipment.	N
4.7.2	In addition to any planned maintenance programme, where there is a risk of product contamination by foreign bodies arising from equipment damage, the equipment shall be inspected at predetermined intervals, inspection results documented and appropriate action taken.	Y
4.7.3	Where temporary repairs are made, these shall be controlled to ensure the safety or legality of product is not jeopardised. These temporary measures shall be permanently repaired as soon as practicable and within a defined timescale.	Y
4.7.4	The company shall ensure that the safety or legality of product is not jeopardised during maintenance and subsequent cleaning operations. Maintenance work shall be followed by a documented hygiene clearance procedure, which records that product contamination hazards have been removed from machinery and equipment.	Y
4.7.5	Materials used for equipment and plant maintenance and that pose a risk by direct or indirect contact with raw materials, intermediate and finished products, such as lubricating oil, shall be food grade.	Y

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4.7.6	Engineering workshops shall be kept clean and tidy and controls shall be in place to prevent contamination risks to the product (e.g. provision of swarf mats at the entrance/exit of workshops).	Y

4.8 Staff facilities

Staff facilities include men and women's restrooms that are segregated from production areas and were sufficient to accommodate the required number of personnel. The facilities were maintained in good and clean condition. Locker rooms were provided for men and women. Personal belongings were stored in lockers in the Locker rooms.

Personnel wore protective clothing over personal clothing. For the high-care area, there were instructions for the order of changing into dedicated protective clothing, dedicated footwear is used in the high care area, smocks were green for the high care and blue for low risk areas.

Hand wash stations are located both outside of the break room and the production line (2 sets of hand sink at the entrance to high care area), as well as within the production areas. Hand-washing facilities were provided in restrooms. The hand wash stations were equipped with sufficient quantity of warm water, liquid soap, single use towels, water taps with hand-free operation, and advisory signs to prompt hand washing.

Smoking was allowed in designated areas outside. Ash trays were provided for butts.

All food brought into manufacturing premises by staff were appropriately stored in a clean and hygienic state in the lunchroom. No food was taken into storage, processing or production areas. Waste containers are present and are adequate for the number of employees.

The vending machine and refrigerator were suitably control.

4.8.5 is N/A due to no high risk areas being present.
4.8.10 is N/A due to no catering occurring on the premises.

Statement of Intent	**Staff facilities shall be sufficient to accommodate the required number of personnel, and shall be designed and operated to minimise the risk of product contamination. The facilities shall be maintained in good and clean condition.**	Y
4.8.1	Designated changing facilities shall be provided for all personnel, whether staff, visitor or contractor. These shall be sited to allow direct access to the production, packing or storage areas without recourse to any external area. Where this is not possible, a risk assessment shall be carried out and procedures implemented accordingly (e.g. the provision of cleaning facilities for footwear).	Y
4.8.2	Storage facilities of sufficient size to accommodate personal items shall be provided for all personnel who work in raw material handling, preparation, processing, packing and storage areas.	Y
4.8.3	Outdoor clothing and other personal items shall be stored separately from workwear within the changing facilities. Facilities shall be available to separate clean and dirty workwear.	Y

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4.8.4	Where an operation includes a high-care area, personnel shall enter via a specially designated changing facility with arrangements to ensure that protective clothing will not be contaminated before entry to the high-care area. The changing facilities shall incorporate the following requirements: • clear instructions for the order of changing into dedicated protective clothes to prevent the contamination of clean clothing • dedicated footwear, by exception shoe coverings shall be provided for visitors only to be worn in the high-care area • an effective system shall be provided to segregate areas for wearing high-care from other footwear (e.g. a barrier or bench system) or there shall be an effective boot wash on entrance to the high-care area • protective clothing shall be visually distinctive from that worn in lower risk areas and shall not be worn outside of the high-care area • hand-washing during the changing procedure shall be incorporated to prevent contamination of the clean protective clothing • on entry to high-care areas,hand-washing and disinfection shall be provided.	Y
4.8.5	Where an operation includes a high-risk area, personnel shall enter via a specially designated changing facility at the entrance to the high-risk area. The changing facilities shall include the following requirements: • clear instructions for the order of changing into dedicated protective clothes to prevent the contamination of clean clothing • dedicated footwear shall be provided to be worn in the high-risk area • an effective system shall be provided to segregate areas for wearing high-risk and other footwear, e.g. a barrier or bench system • protective clothing shall be visually distinctive from that worn in other areas and shall not be worn outside of the high-risk area • hand-washing during the changing procedure shall be incorporated to prevent contamination of the clean protective clothing • on entry to high-risk areas, hand-washing and disinfection shall be provided.	N/A
4.8.6	Suitable and sufficient hand-washing facilities shall be provided at access to, and at other appropriate points within, production areas. Such hand-wash facilities shall provide as a minimum: • sufficient quantity of water at a suitable temperature • liquid soap • single use towels or suitably designed and located air driers • water taps with hand-free operation • advisory signs to prompt hand-washing.	Y
4.8.7	Toilets shall be adequately segregated and shall not open directly into production, packing and storage areas. Toilets shall be provided with hand-washing facilities comprising: • basins with soap and water at a suitable temperature • adequate hand-drying facilities • advisory signs to prompt hand-washing. Where hand-washing facilities within toilet facilities are the only facilities provided before re-entering production, the requirements of 4.8.6 shall apply and signs shall be in place to direct people to hand-wash facilities before entering production.	Y

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4.8.8	Where smoking is allowed under national law, designated controlled smoking areas shall be provided which are both isolated from production areas to an extent that ensures smoke cannot reach the product and fitted with sufficient extraction to the exterior of the building. Adequate arrangements for dealing with smokers' waste shall be provided at smoking facilities, both inside and at exterior locations.	Y
4.8.9	All food brought into manufacturing premises by staff shall be appropriately stored in a clean and hygienic state. No food shall be taken into storage, processing or production areas. Where eating of food is allowed outside during breaks, this shall be in suitable designated areas with appropriate control of waste.	Y
4.8.10	Where catering facilities are provided on the premises, they shall be suitably controlled to prevent contamination of product (e.g. as a source of food poisoning or introduction of allergenic material to the site).	N/A

4.9	**Chemical and physical product contamination conRaw material handling, preparation, processing, packing and storage areas**

Procedures were in place to cover the potential risk of chemical or physical contamination identified in the HACCP Plan and hazard analysis. The Chemical Control Policy, procedure 8.3.1, reviewed 1/6/12 addresses the handling and security required for in-plant chemical. The Approved Chemical Lists were reviewed during the audit.

Confirmed the following chemicals were in the Approved Chemical Lists and MSDS were available for review:
-Madisan 75- sanitizer (Madison Chemicals)
- Dart 444- cleaner (Madison Chemicals)

All chemicals were secure and properly labeled. Strong scented chemicals were not allowed. Only trained personnel used chemicals.

The Knife Safety SOP procedure 7.13 was reviewed. Knives were issues out and inspected each shift. Reviewed the Knife Log for January and February 2012. Staples and paper clips were not permitted within the production areas and none were observed during the site inspection.

The Glass and Hard Plastic procedure SOP 8.5.4 was reviewed. Monthly audits of these materials are conducted by QA. This procedure includes quarantining of product in the area, cleaning the area, changing of clothing and inspection of footwear, authorization to continue production, and record of the incident.

No glass or brittle containers used.

Wood pallets were used in the high-care processing area and for finished products. There was a pallet inspection program in place.

4.1.9.2 is N/A as strong scented chemicals were not used
4.9.3.4.1, .2 and .3 are N/A due to no rigid product containers being used.

Statement of Intent	**Appropriate facilities and procedures shall be in place to control the risk of chemical or physical contamination of product.**	Y

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4.9.1	**Chemical control**	
4.9.1.1	Processes shall be in place to manage the use, storage and handling of non-food chemicals to prevent chemical contamination. These shall include as a minimum: • an approved list of chemicals for purchase • availability of material safety data sheets and specifications • confirmation of suitability for use in a food processing environment • avoidance of strongly scented products • the labelling and/or identification of containers of chemicals at all times • segregated and secure storage with restricted access to authorised personnel • use by trained personnel only.	Y
4.9.1.2	Where strongly scented or taint-forming materials have to be used, for instance for building work, procedures shall be in place to prevent the risk of taint contamination of products.	N/A
4.9.2	**Metal control**	
4.9.2.1	There shall be a documented policy for the control of the use of sharp metal implements including knives, cutting blades on equipment, needles and wires. This shall include a record of inspection for damage and the investigation of any lost items. Snap-off blade knives shall not be used.	Y
4.9.2.2	The purchase of ingredients and packaging which use staples or other foreign-body hazards as part of the packaging materials shall be avoided. Staples and paper clips shall not be used in open product areas. Where staples or other items are present as packaging materials or closures, appropriate precautions shall be taken to minimise the risk of product contamination.	Y
4.9.3	**Glass, brittle plastic, ceramics and similar materials**	
4.9.3.1	Glass or other brittle materials shall be excluded or protected against breakage in areas where open products are handled or there is a risk of product contamination.	Y
4.9.3.2	Documented procedures for handling glass and other brittle materials shall be in place and implemented to ensure that necessary precautions are taken. Procedures shall include as a minimum: • a list of items detailing location, number, type and condition • recorded checks of condition of items, carried out at a specified frequency that is based on the level of risk to the product • details on cleaning or replacing items to minimise potential for product contamination.	Y

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4.9.3.3	Documented procedures detailing the action to be taken in case of breakage of glass or other brittle items shall be implemented and include the following: • quarantining the products and production area that were potentially affected • cleaning the production area • inspecting the production area and authorising to continue production • changing of workwear and inspection of footwear • specifying those staff authorised to carry out the above points • recording the breakage incident.	Y
4.9.3.4	**Products packed into glass or other brittle containers**	
4.9.3.4.1	The storage of the containers shall be segregated from the storage of raw materials, product or other packaging.	N/A
4.9.3.4.2	Systems shall be in place to manage container breakages between the container cleaning/inspection point and container closure. This shall include, as a minimum, documented instructions which ensure: • the removal and disposal of at-risk products in the vicinity of the breakage; this may be specific for different equipment or areas of the production line. • the effective cleaning of the line or equipment which may be contaminated by fragments of the container. Cleaning shall not result in the further dispersal of fragments, for instance by the use of high pressure water or air. • the use of dedicated, clearly identifiable cleaning equipment (e.g. colour coded) for removal of container breakages. Such equipment shall be stored separately from other cleaning equipment. • the use of dedicated, accessible lidded waste containers for the collection of damaged containers and fragments. • a documented inspection of production equipment is undertaken following the cleaning of a breakage to ensure cleaning has effectively removed any risk of further contamination. • authorisation is given for production to re-start following cleaning. • the area around the line is kept clear of broken glass.	N/A
4.9.3.4.3	Records shall be maintained of all container breakages on the line. Where no breakages have occurred during a production period, this shall also be recorded. This record shall be reviewed to identify trends and potential line or container improvements.	N/A
4.9.4	**Wood**	
4.9.4.1	Wood should not be used in open product areas except where this is a process requirement (e.g. maturation of products in wood). Where the use of wood cannot be avoided, the condition of wood shall be continually monitored to ensure it is in good condition and free from damage or splinters which could contaminate products.	Y

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4.10	Foreign body detection and removal equipment	

The company uses metal detection for foreign body detection and removal as described in SOP 8.5.1 dated 5/5/14. Metal detection has been deemed a CCP for the processes in this plant.

Test Pieces in use were:
-Ferrous 2.0 mm, Organic, 2.5 mm
-Non Ferrous 3.0 mm, Organic, 2.5 mm
-Stainless Steel 3.5 mm, Organic, 3.5 mm

All products pass through a functioning metal detector before shipping. Metal detectors were challenged at beginning of shift, hourly, end of the shift and at product change. Checks included re-set and memory function tests. Where the metal detector detected foreign material, the source of any unexpected material was investigated. Information on rejected materials was used to identify trends.

Rejected product was removed for the process flow via a retractable conveyor or pushed off by a rejecting mechanism and isolated in a rejection container.

Records were reviewed for January and February 2015. Metal detector test failures were documented on a deviation report. Should a test fail, the line was stopped and Quality and maintenance were notified. Product was placed on hold back to the last acceptable test and run back through a functioning metal detector. The product was managed per the Non-Conforming Product procedure.

The facility uses two optical sorting machines when it runs organic tender leaf product on lines 1 and 2.

The Optical Sorter SOP procedure was reviewed. The sorter functionality was confirmed every hours and documented on the Optical Sorted / Ray Tec Verification form.

4.10.2.1, and .2, is N/A due to no filters or sieves being used
4.10.4 is N/A as magnets are not used
4.10.6.1 and .2 are N/A due to no container cleaning equipment being used

Statement of Intent	**The risk of product contamination shall be reduced or eliminated by the effective use of equipment to remove or detect foreign bodies.**	Y
4.10.1.1	A documented assessment in association with the HACCP study shall be carried out on each production process to identify the potential use of equipment to detect or remove foreign body contamination. Typical equipment to be considered may include: • filters • sieves • metal detection • magnets • optical sorting equipment • X-ray detection equipment • other physical separation equipment e.g. gravity separation, fluid bed technology.	Y

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4.10.1.2		The type, location and sensitivity of the detection and/or removal method shall be specified as part of the company's documented system. Industry best practice shall be applied with regard to the nature of the ingredient, material, product and/or the packed product. The location of the equipment or any other factors influencing the sensitivity of the equipment shall be validated and justified.	Y
4.10.1.3		The company shall ensure that the frequency of the testing of the foreign body detection and/or removal equipment is defined and takes into consideration: • specific customer requirements • the company's ability to identify, hold and prevent the release of any affected materials, should the equipment fail.	Y
4.10.1.4		Where foreign material is detected or removed by the equipment, the source of any unexpected material shall be investigated. Information on rejected materials shall be used to identify trends and where possible instigate preventive action to reduce the occurrence of contamination by the foreign material.	Y

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4.10.6.1 and .2 are N/A due to no container cleaning equipment being used

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Statement of Intent	**The risk of product contamination shall be reduced or eliminated by the effective use of equipment to remove or detect foreign bodies.**	Y
4.10.1.1	A documented assessment in association with the HACCP study shall be carried out on each production process to identify the potential use of equipment to detect or remove foreign body contamination. Typical equipment to be considered may include: • filters • sieves • metal detection • magnets • optical sorting equipment • X-ray detection equipment • other physical separation equipment e.g. gravity separation, fluid bed technology.	Y
4.10.1.2	The type, location and sensitivity of the detection and/or removal method shall be specified as part of the company's documented system. Industry best practice shall be applied with regard to the nature of the ingredient, material, product and/or the packed product. The location of the equipment or any other factors influencing the sensitivity of the equipment shall be validated and justified.	Y
4.10.1.3	The company shall ensure that the frequency of the testing of the foreign body detection and/or removal equipment is defined and takes into consideration: • specific customer requirements • the company's ability to identify, hold and prevent the release of any affected materials, should the equipment fail.	Y
4.10.1.4	Where foreign material is detected or removed by the equipment, the source of any unexpected material shall be investigated. Information on rejected materials shall be used to identify trends and where possible instigate preventive action to reduce the occurrence of contamination by the foreign material.	Y
4.10.2	**Filters and sieves**	
4.10.2.1	Filters and sieves used for foreign body control shall be of a specified mesh size or gauge and designed to provide the maximum practical protection for the product. Material retained or removed by the system shall be examined and recorded to identify contamination risks.	N/A
4.10.2.2	Filters and sieves shall be regularly inspected or tested for damage on a documented frequency based on risk. Records shall be maintained of the checks. Where defective filters or sieves are identified this shall be recorded and the potential for contamination of products investigated and appropriate action taken.	N/A

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GLOBAL STANDARD FOR FOOD SAFETY

4.10.3	Metal detectors and X-ray equipment	
4.10.3.1	Metal detection equipment shall be in place unless risk assessment demonstrates that this does not improve the protection of final products from metal contamination. Where metal detectors are not used justification shall be documented. The absence of metal detection would only normally be based on the use of an alternative, more effective, method of protection (e.g. use of X-ray, fine sieves or filtration of products).	Y
4.10.3.2	Where metal detectors or X-ray equipment is used, this shall be situated at the latest practical step in the process flow and, wherever possible, after the product has been packaged.	Y
4.10.3.3	The metal detector or X-ray equipment shall incorporate one of the following: • an automatic rejection device, for continuous in-line systems, which shall either divert contaminated product out of the product flow or to a secure unit accessible only to authorised personnel • a belt stop system with an alarm where the product cannot be automatically rejected, e.g. for very large packs • in-line detectors which identify the location of the contaminant shall be operated to allow effective segregation of the affected product.	Y
4.10.3.4	The company shall establish and implement documented procedures for the operation and testing of the metal or X-ray equipment. This shall include as a minimum: • responsibilities for the testing of equipment • the operating effectiveness and sensitivity of the equipment and any variation to this for particular products • the methods and frequency of checking the detector • recording of the results of checks.	Y
4.10.3.5	Metal detector checking procedures shall be based on best practice and shall as a minimum include: • use of test pieces incorporating a sphere of metal of a known diameter. The test pieces shall be marked with the size and type of test material contained. • tests carried out using separate test pieces containing ferrous metal, stainless steel and typically non-ferrous metal, unless the product is within a foil container. • a test that both the detection and rejection mechanisms are working effectively under normal working conditions. • checks that test the memory/reset function of the metal detector by passing successive test packs through the unit. • In addition, where metal detectors are incorporated on conveyors: • the test piece shall be passed as close as possible to the centre of the metal detector aperture and wherever possible be carried out by inserting the test piece within a clearly identified sample pack of the food being produced at the time of the test. Where in-line metal detectors are used the test piece shall be placed in the product flow wherever this is possible.	Y

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4.10.3.6		The company shall establish and implement corrective action and reporting procedures in the event of the testing procedure identifying any failure of the foreign body detector. Action shall include a combination of isolation, quarantining and re-inspection of all product produced since the last successful test.	Y
4.10.4		**Magnets**	
4.10.4.1		The type, location and the strength of magnets shall be fully documented. Documented procedures shall be in place for the inspection, cleaning, strength testing and integrity checks. Records of all checks shall be maintained.	N/A
4.10.5		**Optical sorting equipment**	
4.10.5.1		Each unit shall be checked in accordance with the manufacturer's instructions or recommendations. Checks shall be documented.	Y
4.10.6		**Container cleanliness – glass jars, cans and other rigid containers**	
4.10.6.1		Based on risk assessment, procedures shall be implemented to minimise foreign body contamination originating with the packaging container (e.g. jars, cans and other preformed rigid containers). This may include the use of covered conveyors, container inversion and foreign body removal through rinsing with water or air jets.	N/A
4.10.6.2		The effectiveness of the container cleaning equipment shall be checked and recorded during each production. Where the system incorporates a rejection system for dirty or damaged containers, the check shall incorporate a test of both the detection and effective rejection of the test container.	N/A

4.11 HOUSEKEEPING AND HYGIENE

A Sanitation and Hygiene Program SOP 8.3.1 was in place. Housekeeping and cleaning systems are in place which ensure appropriate standards of hygiene are maintained at all times and that risk of contamination is minimized.

The site operates a 'clean as you go' policy during production hours with a full clean at the end of production. Satisfactory standards of hygiene were seen throughout the site inspection. Documented cleaning procedures are available in the factory. Methods have been developed in conjunction with the supplier of the sanitation chemicals. The cleaning methods include responsibility, areas to be cleaned, cleaning frequency, cleaning methods, materials to be used, records and verification system.

The sanitation crew is made up of 24 company employees. Chemicals are purchased from Madison Chemical (Approved supplier) and controlled through procedures that have been developed. MSDS sheets were seen during the audit for a cleaner and a sanitizer. Letters of Guarantee from the chemical company are on file.

Records of all cleaning activities are retained by the site. Areas receive a full cleaning at the end of the production and prepared for

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the next day's operation. Reviewed the cleaning pre-op sheets during the pre-op inspection on the second day of the audit. T he Master Cleaning Schedule was also reviewed and was seen to be updated. The effectiveness of cleaning is assessed visually and with ATP swabs immediately following cleaning and during the pre-production start up checks. Areas requiring corrective action are re-cleaned. Equipment and environmental swabs are sent for testing to the lab on a programmed schedule. Reviewed training for chemicals and sanitation training. Also reviewed were Food Safety meeting notes. No trends were evident and swab counts are low. Cleaning equipment was color coded. High-care cleaning equipment was dedicated to the high-care areas. Currently CIP systems are not utilized at this location. 4.11.6.1, .2 and .3 are N/A as there is no CIP system in use in this facility.		
FUNDAMENTAL Statement of Intent	**Housekeeping and cleaning systems shall be in place which ensure appropriate standards of hygiene are maintained at all times and the risk of product contamination is minimised.**	Y
4.11.1	Documented cleaning procedures shall be in place and maintained for the building, plant and all equipment. Cleaning procedures shall as a minimum include the: • responsibility for cleaning • item/area to be cleaned • frequency of cleaning • method of cleaning, including dismantling equipment for cleaning purposes where required • cleaning chemicals and concentrations • cleaning materials to be used • cleaning records and responsibility for verification. The frequency and methods of cleaning shall be based on risk. The procedures shall be implemented to ensure appropriate standards of cleaning are achieved.	Y
4.11.2	Limits of acceptable and unacceptable cleaning performance shall be defined, based on the potential hazards (e.g. microbiological, allergen or foreign body contamination). Acceptable levels of cleaning may be defined by visual appearance, ATP bioluminescence techniques (see Glossary), microbiological testing or chemical testing as appropriate. The cleaning and disinfection procedures and frequency shall be validated and records maintained.	Y
4.11.3	The resources for undertaking cleaning shall be available. Where it is necessary to dismantle equipment for cleaning purposes or to enter large equipment for cleaning, this shall be appropriately scheduled and, where necessary, planned for non-production periods. Cleaning staff shall be adequately trained or engineering support provided where access within equipment is required for cleaning.	Y

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4.11.4		The cleanliness of equipment shall be checked before equipment is released back into full production. The results of checks on cleaning, including visual, analytical and microbiological checks, shall be recorded and used to identify trends in cleaning performance and instigate improvements where required.	Y
4.11.5		Cleaning equipment shall be: • fit for purpose • suitably identified for intended use, e.g. colour coded or labelled • cleaned and stored in a hygienic manner to prevent contamination. Equipment used for cleaning in high-care and high-risk areas shall be dedicated for use in that area.	Y
4.11.6	**Cleaning in place (CIP)**		
4.11.6.1		Cleaning-in-place (CIP) facilities, where used, shall be monitored and maintained to ensure their effective operation.	N/A
4.11.6.2		A schematic plan of the layout of the CIP system shall be available. There shall be an inspection report or other verification that: • systems are hygienically designed with no dead areas, limited interruptions to flow streams and good system drain ability. • scavenge pumps are operated to ensure that there is no build-up of cleaning fluids in the vessels. • spray balls effectively clean vessels by providing full surface coverage and are periodically inspected for blockages. Rotating spray devices should have a defined operational time. • CIP equipment has adequate separation from active product lines, e.g. through the use of double seat valves, manually controlled links or blanks in pipework. The system shall be revalidated following alterations or additions to the CIP equipment. A log of changes to the CIP system shall be maintained.	N/A
4.11.6.3		The CIP equipment shall be operated to ensure effective cleaning is carried out: • The process parameters, time, detergent concentrations, flow rate and temperatures shall be defined to ensure removal of the appropriate target hazard, e.g. soil, allergens, vegetative microorganisms, spores. This shall be validated and records of the validation maintained. • Detergent concentrations shall be checked routinely. • Process verification shall be undertaken by analysis of rinse waters and/or first product through the line for the presence of cleaning fluids or by tests of ATP (bioluminescence techniques) allergens or micro-organisms as appropriate. • Detergent tanks shall be kept stocked up and a log maintained of when these are filled and emptied. Recovered pre-rinse solutions shall be monitored for a build-up of carry-over from the detergent tanks. • Filters, where fitted, shall be cleaned and inspected at a defined frequency.	N/A

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BRC GLOBAL STANDARD FOR FOOD SAFETY

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4.12	Waste/waste disposal	
	The waste collection areas were observed to be clean and well-maintained during this assessment. No waste accumulation was noted. An approved contractor – All Waste Services, Inc. removed waste trash. Animal feed is removed by company trucks. Waste containers inside the facility as well as the main dumpster are maintained in good condition and identified appropriately. Document control contains the retention procedure for control of any trademarked materials.	
4.12.1	Waste disposal shall be managed in accordance with legal requirements and to prevent accumulation, risk of contamination and the attraction of pests.	Y
4.12.2	Food Products intended to be supplied for animal feed shall be segregated from waste and managed in accordance with the relevant legislative requirements.	Y
4.12.3	External waste collection containers and rooms housing waste facilities shall be managed to minimise risk. These shall be: • clearly identified • designed for ease of use and effective cleaning • well-maintained to allow cleaning and, where required, disinfection • emptied at appropriate frequencies • covered or doors kept closed as appropriate.	Y
4.12.4	If unsafe products or substandard trademarked materials are transferred to a third party for destruction or disposal, that third party shall be a specialist in secure product or waste disposal and shall provide records which includes the quantity of waste collected for destruction or disposal.	Y
4.13	Pest control	
	The facility contracts with the Orkin Pest Management Services, for interior and exterior rodent and insect control. A signed agreement is in place and specifies interior and exterior rodent service. The business license was on file, along with a copy of the liability insurance and PCO applicator licenses. Rodents, crawling insects, and flying insects were covered in the contract. All documentation was seen to be complete. T he site map dated November 21, 2014 indicated the positions of all pest control devices. The frequency of service visits was weekly for the interior traps of the plant and monthly for the exterior bait stations. There are 136 interior traps, (including 6 ILT Lights) and 128 exterior bait traps. External bait stations were plastic boxes secured in place. ILT units	

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were well sited, and provided with a glue board that eliminated the potential for expel issues. Review of the last 4 months of records showed there have been no catches in the plant.

Trending is done after each visit, uploaded to the Share Point System and reviewed quarterly as part of the service agreement. No evidence of infestation was observed on the plant inspection or has recently been reported. All pest control activities are performed by the pest control contractor.

By policy, documented pest control surveys with the pest control company's corporate personnel are to be conducted quarterly. The most recent survey was performed on March 9, 2015.

The chemicals used were all EPA approved MSDS was checked for:
-Termidor SC
-Contrac-Blox

4.13.2 is N/A as pest control is a contracted service.

Statement of Intent	**The whole site shall have an effective preventive pest control programme in place to minimise the risk of infestation and there shall be the resources available to rapidly respond to any issues which occur to prevent risk to products.**	Y
4.13.1	The company shall either contract the services of a competent pest control organisation, or shall have appropriately trained staff, for the regular inspection and treatment of the site to deter and eradicate infestation. The frequency of inspections shall be determined by risk assessment and shall be documented. Where the services of a pest control contractor are employed, the service contract shall be clearly defined and reflect the activities of the site.	Y
4.13.2	Where a company undertakes its own pest control, it shall be able to effectively demonstrate that: • pest control operations are undertaken by trained and competent staff with sufficient knowledge to select appropriate pest control chemicals and proofing methods and understand the limitations of use, relevant to the biology of the pests associated with the site • sufficient resources are available to respond to any infestation issues • there is ready access to specialist technical knowledge when required • legislation governing the use of pest control products is understood • dedicated locked facilities are used for the storage of pesticides.	N/A

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4.13.3	Pest control documentation and records shall be maintained. This shall include as a minimum: • an up-to-date plan of the full site identifying numbered pest control device locations • identification of the baits and/or monitoring devices on site • clearly defined responsibilities for site management and for the contractor • details of pest control products used, including instructions for their effective use and action to be taken in case of emergencies • any observed pest activity • details of pest control treatments undertaken.	Y
4.13.4	Bait stations shall be robust, of tamper resistant construction, secured in place and appropriately located to prevent contamination risk to product. Missing bait boxes shall be recorded, reviewed and investigated. Toxic rodent baits shall not be used within production areas or storage areas where open product is present except when treating an active infestation.	Y
4.13.5	Fly-killing devices and/or pheromone traps shall be correctly sited and operational. If there is a danger of insects being expelled from a fly-killing extermination device and contaminating the product, alternative systems and equipment shall be used.	Y
4.13.6	In the event of infestation, or evidence of pest activity, immediate action shall be taken to eliminate the hazard. Any potentially affected products should be subject to the non-conforming product procedure.	Y
4.13.7	Records of pest control inspections, pest proofing and hygiene recommendations and actions taken shall be maintained. It shall be the responsibility of the company to ensure all of the relevant recommendations made by their contractor or in-house expert are carried out in a timely manner.	Y
4.13.8	An in-depth, documented pest control survey shall be undertaken at a frequency based on risk, but typically quarterly, by a pest control expert to review the pest control measures in place. The timing of the survey shall be such as to allow access to equipment for inspection where a risk of stored product insect infestation exists.	Y
4.13.9	Results of pest control inspections shall be assessed and analysed for trends on a regular basis, but as a minimum: • in the event of an infestation • annually This shall include a catch analysis from trapping devices to identify problem areas. The analysis shall be used as a basis for improving the pest control procedures.	Y

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GLOBAL STANDARD FOR FOOD SAFETY

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4.14	Storage facilities	

Storage areas are dry and well ventilated. Raw materials, packaging and finished products are stored separately.

The Facility Temperature Procedure SOP 5.3 was reviewed. Tomato storage areas were maintained at 45-60F. All other coolers were 33-40F. The Finished Product Requirements on Storage procedure was reviewed.

Maintenance manually recorded temperatures daily. Temperatures were also continuously monitored electronically.

All materials and products were observed to be stored off the ground and away from walls. No controlled atmosphere or outside storage.

Stock rotation was managed by an electronic inventory FIFO system.

All materials were clearly labeled to ensure proper trace and stock rotation.

4.14.4 is N/A as there is no outside storage.

Statement of Intent	**All facilities used for the storage of ingredients, in-process product and finished products shall be suitable for its purpose.**	Y
4.14.1	Documented procedures to maintain product safety and quality during storage shall be developed on the basis of risk assessment, understood by relevant staff and implemented accordingly. These may include as appropriate: • managing chilled and frozen product transfer between temperature controlled areas • segregation of products where necessary to avoid cross-contamination (physical, microbiological or allergens) or taint uptake • storing materials off the floor and away from walls • specific handling or stacking requirements to prevent product damage.	Y
4.14.2	Where temperature control is required, the storage area shall be capable of maintaining product temperature within specification and operated to ensure specified temperatures are maintained. Temperature recording equipment with suitable temperature alarms shall be fitted to all storage facilities or there shall be a system of recorded manual temperature checks, typically on at least a four-hourly basis or at a frequency which allows for intervention before product temperatures exceed defined limits for the safety, legality or quality of products.	Y
4.14.3	Where controlled atmosphere storage is required, the storage conditions shall be specified and effectively controlled. Records shall be maintained of the storage conditions.	Y
4.14.4	Where storage outside is necessary, items shall be protected from contamination and deterioration.	N/A

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4.14.5	Receipt documents and/or product identification shall facilitate correct stock rotation of raw materials, intermediate products and finished products in storage and ensure materials are used in the correct order in relation to their manufacturing date and within the prescribed shelf life.	Y

4.15 Dispatch and transport

Dispatch and transport requirements are defined in the Materials Storage and Transport Policy SOP 6.7 dated 3/9/15. The Great Plains Electronic system holds the information of the shipped product.

Storage, transport and dispatch areas on the site were noted to be suitable and in a satisfactory condition. Procedures are in place to maintain product safety (locks and seals) and quality during storage, loading and transportation. The procedures detail vehicle inspection for cleanliness and suitability, including segregation, prior to loading and unloading, and the monitoring of temperatures where appropriate.

Records are maintained. The ability to trace trucks was reviewed in the vertical trace exercise in 3.9 and found to be in compliance. The pre-load checklist was reviewed with the truck-loading employee on the first day of the audit. Trailer was pre-cooled to 34F before loading as processed product was to be loaded on the truck.

Temperature recorders are places on each truck to monitor temperatures during transport. Specialized customer directions are followed (use of blankets, bagging) to protect the product.

Organic product is picked up by the customer. All other product outbound is shipped on company trucks.

Statement of Intent	**Procedures shall be in place to ensure that the management of dispatch and of the vehicles and containers used for transporting products from the site do not present a risk to the safety or quality of the products.**	Y
4.15.1	Documented procedures to maintain product safety and quality during loading and transportation shall be developed and implemented. These may include as appropriate: • controlling temperature of loading dock areas • the use of covered bays for vehicle loading or unloading • securing loads on pallets to prevent movement during transit • inspection of loads prior to dispatch.	Y
4.15.2	Traceability shall be ensured during transportation. There shall be a clear record of dispatch and receipt of goods and materials demonstrating that sufficient checks have been completed during the transfer of goods.	Y

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4.15.3	All vehicles or containers used for the dispatch of products shall be inspected prior to loading to ensure that they are fit for purpose. This shall ensure that they are: • in a suitably clean condition • free from strong odours which may cause taint to products • suitably maintained to prevent damage to products during transit • equipped to ensure any temperature requirements can be maintained. Records of inspections shall be maintained.	Y
4.15.4	Where temperature control is required, the transport shall be capable of maintaining product temperature within specification, under minimum and maximum load. Temperature data-logging devices which can be interrogated to confirm time/temperature conditions or a system to verify and record at predetermined frequencies the correct operation of refrigeration equipment shall be used and records maintained.	Y
4.15.5	Maintenance systems and documented cleaning procedures shall be maintained for all vehicles and equipment used for loading/unloading (e.g. hoses connecting to silo installations). There shall be records of the measures taken.	Y
4.15.6	The company shall have documented procedures for the transport of products, which shall include: • any restrictions on the use of mixed loads • requirements for the security of products during transit, particularly when vehicles are parked and unattended • clear instructions in the case of vehicle breakdown, accident or failure of refrigeration systems which ensure the safety of the products is assessed and records maintained.	Y
4.15.7	Where the company employs third-party contractors, all the requirements specified in this section shall be clearly defined in the contract and verified or the contracted company shall be certificated to the Global Standard for Storage and Distribution or similar internationally recognised Standard.	Y

5 Product Control

Product design and development procedures (also called the Red Folder) were in place for new products or processes and any changes to product, packaging or manufacturing processes to ensure that safe and legal products were produced.

The Facility Trial and Process Changes procedure was reviewed. All changes and new products were evaluated through the HACCP system and the team. Trials using production equipment were carried out. The Conventional Shelf Life Protocol version 1 was reviewed.

New products were tested for visual, flavor, texture and bag leakage. All products were labeled to meet legal requirements for the USA and included information to allow the safe handling, storage and use. No exported products.

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The site was certified by QAI to manufacture organic products. No claims are made by the facility.		
5.1	Product design and development procedures shall be in place for new products or processes and any changes to product, packaging or manufacturing processes to ensure that safe and legal products are produced.	Y
5.1.1	The company shall provide clear guidelines on any restrictions to the scope of new product developments to control the introduction of hazards which would be unacceptable to the company or customers (e.g. the introduction of allergens, glass packaging or microbiological risks).	Y
5.1.2	All new products and changes to product formulation, packaging or methods of processing shall be formally approved by the HACCP team leader or authorised HACCP committee member. This shall ensure that hazards have been assessed and suitable controls, identified through the HACCP system, are implemented. This approval shall be granted before products are introduced into the factory environment.	Y
5.1.3	Trials using production equipment shall be carried out where it is necessary to validate that product formulation and manufacturing processes are capable of producing a safe product of the required quality.	Y
5.1.4	Shelf-life trials shall be undertaken using documented protocols reflecting conditions experienced during storage and handling. Results shall be recorded and retained and shall confirm compliance with relevant microbiological, chemical and organoleptic criteria. Where shelf-life trials prior to production are impractical, for instance for some long-life products, a documented science-based justification for the assigned shelf life shall be produced.	Y
5.1.5	All products shall be labelled to meet legal requirements for the designated country of use and shall include information to allow the safe handling, display, storage, preparation and use of the product within the food supply chain or by the customer. There shall be a process to verify that ingredient and allergen labelling is correct based on the product recipe.	Y
5.1.6	Where a product is designed to enable a claim to be made to satisfy a consumer group (e.g. a nutritional claim, reduced sugar), the company shall ensure that the product formulation and production process is fully validated to meet the stated claim.	N/A
5.2	**MANAGEMENT OF ALLERGENS**	
There was an allergen control program in place SOP 4.10 updated 3/9/2015. The facility does not process allergen containing materials. All employees are given allergen awareness training prior to beginning work at the plant and as part of their annual refresher training. Allergen free claims are not made. Allergen disclosure and programs are required of suppliers as per the vendor approval program.		

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5.2.7 is N/A as no claim of these products suitability for allergy suffers is made. 5.2.2, .3, .4, .5, .6, .8 is N/A due to no allergen present at this facility.		
FUNDAMENTAL Statement of Intent	**The company shall have a developed system for the management of allergenic materials which minimises the risk of allergen contamination of products and meets legal requirements for labelling.**	Y
5.2.1	The company shall carry out an assessment of raw materials to establish the presence and likelihood of contamination by allergens (refer to glossary). This shall include review of raw material specifications and, where required, obtain additional information from suppliers, for example through questionnaires to understand the allergen status of the raw material, its ingredients and the factory in which it is produced.	Y
5.2.2	The company shall identify and list allergen-containing materials handled on site. This shall include raw materials, processing aids, intermediate and finished products and any new product development ingredients or products.	N/A
5.2.3	A documented risk assessment shall be carried out to identify routes of contamination and establish documented policies and procedures for handling raw materials, intermediate and finished products to ensure cross-contamination is avoided. This shall include: • consideration of the physical state of the allergenic material, i.e. powder, liquid, particulate • identification of potential points of cross-contamination through the process flow • assessment of the risk of allergen cross-contamination at each process step • identification of suitable controls to reduce or eliminate the risk of cross-contamination.	N/A
5.2.4	Documented procedures shall be established to ensure the effective management of allergenic materials to prevent cross-contamination into products not containing the allergen. This shall include as appropriate: • physical or time segregation whilst allergen-containing materials are being stored, processed or packed • the use of separate or additional protective over clothing when handling allergenic materials • use of identified, dedicated equipment and utensils for processing • scheduling of production to reduce changes between products containing an allergen and products not containing the allergen • systems to restrict the movement of airborne dust containing allergenic material • waste handling and spillage controls • restrictions on food brought onto site by staff, visitors, contractors and for catering purposes.	N/A
5.2.5	Where rework is used, or reworking operations carried out, procedures shall be implemented to ensure rework containing allergens is not used in products that do not already contain the allergen.	N/A

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5.2.6	Where the nature of the production process is such that cross-contamination from an allergen cannot be prevented, a warning shall be included on the label. National guidelines or codes of practice shall be used when making such a warning statement.	N/A
5.2.7	Where a claim is made regarding the suitability of a food for allergy or food sensitivity sufferers, the company shall ensure that the production process is fully validated to meet the stated claim. This shall be documented.	N/A
5.2.8	Equipment or area cleaning procedures shall be designed to remove or reduce to acceptable levels any potential cross-contamination by allergens. The cleaning methods shall be validated to ensure they are effective and the effectiveness of the procedure routinely verified. Cleaning equipment used to clean allergenic materials shall either be identifiable and specific for allergen use, single use, or effectively cleaned after use.	N/A
5.2.9	All relevant personnel, including engineers, temporary staff and contractors, shall have received general allergen awareness training and be trained in the company's allergen-handling procedures.	Y
5.2.10	An effective system of documented checks shall be in place at line start-up, following product changeover and changes in batches of packaging to ensure that the labels applied are correct for the products packed.	Y
5.3	**Provenance, assured status and claims of identity preserved materials**	
This section is N/A as no claims of provenance, assured status or claims of identity preserved materials are claimed.		
Statement of Intent	**Systems of traceability, identification and segregation of raw materials, intermediate and finished products shall be in place to ensure that all claims relating to provenance or assured status can be substantiated.**	**N/A**
5.3.1	Where claims are to be made on finished packs about the provenance, assured or 'identity preserved' status (see Glossary) of raw materials used, the status of each batch of the raw material shall be verified and records maintained.	N/A
5.3.2	Where a claim is made relating to the provenance, assured or identity preserved status of a product or ingredient, the facility shall maintain purchasing records, traceability of raw material usage and final product packing records to substantiate claims. The company shall undertake documented mass balance tests at least every six months and at a frequency to meet the particular scheme requirements.	N/A

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5.3.3		The process flow for the production of products where claims are made shall be documented and potential areas for contamination or loss of identity identified. Appropriate controls shall be established to ensure the integrity of the product claims.	N/A

5.4 Product Packaging

Storage areas were observed during the tour. All areas were clean and picked up. Packaging materials are stored away from finished products and raw materials. Combo liners were colored.

Letters of Conformity were seen during the vertical trace exercise. An approved supplier list is followed. The parameters of use for the packaging were found in the letters. When a specification for a product is reviewed the packaging and label specs are reviewed and are part of the new product specification.

One minor non conformity was raised against this section.

Statement of Intent	**Product packaging shall be appropriate for the intended use and shall be stored under conditions to minimise contamination and deterioration.**	Y
5.4.1	When purchasing or specifying food contact packaging the supplier of packaging materials shall be made aware of any particular characteristics of the food (e.g. high fat content, pH or usage conditions such as microwaving) which may affect packaging suitability. Certificates of conformity or other evidence shall be available for product packaging to confirm it conforms to relevant food safety legislation and is suitable for its intended use.	Y
5.4.2	Where appropriate, packaging shall be stored away from raw materials and finished product. Any part-used packaging materials suitable for use shall be effectively protected from contamination and clearly identified before being returned to an appropriate storage area. Obsolete packaging shall be stored in a separate area and systems shall be in place to prevent accidental use.	N
5.4.3	Product contact liners (or raw material/work-in-progress contact liners) purchased by the company shall be appropriately coloured and resistant to tearing to prevent accidental contamination.	Y

5.5 Product inspection and laboratory testing

Inspection and analysis critical to product safety, legality and quality are undertaken. Risk assessment has determined that the finished product is tested in line with a pre-determined schedule to SOPs and HACCP requirements.

Samples are tested for specification and sensory. Specific product testing is detailed within each individual product specification.

Testing and inspection records are reviewed by Quality Assurance and Production management. Sensory assessments are conducted against a specification with pre-determined attributes. Tests are recorded with corrective actions according to Quality Risk Assessment.

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Pathogenic testing is done by an outside regional laboratory that is certified ISO 17025:2005. AOAC procedures are used at the plant laboratory. Proficiency testing takes place.		
Statement of Intent	**The company shall undertake or subcontract inspection and analyses which are critical to confirm product safety, legality and quality, using appropriate procedures, facilities and standards.**	Y
5.5.1	**Product inspection and testing**	
5.5.1.1	There shall be a scheduled programme of testing covering products and the processing environment which may include microbiological, chemical, physical and organoleptic testing according to risk. The methods, frequency and specified limits shall be documented.	Y
5.5.1.2	Test and inspection results shall be recorded and reviewed regularly to identify trends. Appropriate actions shall be implemented promptly to address any unsatisfactory results or trends.	Y
5.5.1.3	The company shall ensure that a system of on-going shelf-life assessment is in place. This shall be based on risk and shall include microbiological and sensory analysis as well as relevant chemical factors such as pH and aw. Records and results from shelf life tests shall validate the shelf life period indicated on the product.	Y
5.5.2	**Laboratory testing**	
5.5.2.1	Pathogen testing shall be subcontracted to an external laboratory or, where conducted internally, the laboratory facility shall be fully segregated from the manufacturing site and have operating procedures to prevent any risk of product contamination.	Y
5.5.2.2	Where routine testing laboratories are present on a manufacturing site, they shall be located, designed and operated to eliminate potential risks to product safety. Controls shall be documented, implemented and shall include consideration of the following: • design and operation of drainage and ventilation systems • access and security of the facility • movement of laboratory personnel • protective clothing arrangements • processes for obtaining product samples • disposal of laboratory waste.	Y

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5.5.2.3	Where the company undertakes or subcontracts analyses which are critical to product safety or legality, the laboratory or subcontractors shall have gained recognised laboratory accreditation or operate in accordance with the requirements and principles of ISO 17025. Documented justification shall be available where accredited methods are not undertaken.	Y
5.5.2.4	Procedures shall be in place to ensure reliability of laboratory results, other than those critical to safety and legality specified in 5.5.2.3. These shall include: • use of recognised test methods, where available • documented testing procedures • ensuring staff are suitably qualified and/or trained and competent to carry out the analysis required • use of a system to verify the accuracy of test results, e.g. ring or proficiency testing • use of appropriately calibrated and maintained equipment.	Y

5.6 Product release

A HACCP record review is required for release for all products. Products are available for release as soon as packaged and documents have been reviewed. One customer requires positive release. Products shipped to this customer were seen in the designated hold area awaiting lab results and appropriate disposal.

QA Manager or designate may release the product after all testing results finished and within specifications.

5.6.1	Where products require positive release, procedures shall be in place to ensure that release does not occur until all release criteria have been completed and release authorised.	Y
Statement of Intent	**The company shall ensure that finished product is not released unless all agreed procedures have been followed.**	Y

6 PROCESS CONTROL

Production specifications, procedures and work instructions were clearly documented.

Work instruction documents were reviewed during the traceability exercise and while conducting the plant inspection. The work instructions were seen to be very detailed with photographs; videos and color illustrations used as visual aids and were posted at work stations.

Reviewed specifications and blending instructions and production schedules. The blending instructions informed the staff of what product and how much to use. The production schedule included packaging, coding and weight information.

Flume water was maintained at 33-40F and was verified by QA hourly. The addition of chlorine to the flume water was automated, but monitored by QA. Corrective action and non-conforming product procedures were in place in the event of process failure.

Documented checks of the production line were carried out before commencing production and following changes of product.

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FUNDAMENTAL Statement of Intent	**The company shall operate to documented procedures and/or work instructions that ensure the production of consistently safe and legal product with the desired quality characteristics, in full compliance with the HACCP food safety plan.**	N/A
6.1.1	Documented process specifications and work instructions shall be available for the key processes in the production of products to ensure product safety, legality and quality. The specifications as appropriate shall include: • recipes – including identification of any allergens • mixing instructions, speed, time • equipment process settings • cooking times and temperatures • cooling times and temperatures • labelling instructions • coding and shelf life marking • any additional critical control points identified in the HACCP plan.	N/A
6.1.2	Process monitoring, such as of temperature, time, pressure and chemical properties, shall be implemented, adequately controlled and recorded to ensure that product is produced within the required process specification.	N/A
6.1.3	In circumstances where process parameters are controlled by in-line monitoring devices, these shall be linked to a suitable failure alert system that is routinely tested.	N/A
6.1.4	Where variation in processing conditions may occur within equipment critical to the safety or quality of products, the processing characteristics shall be validated at a frequency based on risk and performance of equipment (e.g. heat distribution in retorts, ovens and processing vessels; temperature distribution in freezers and cold stores).	N/A
6.1.5	In the case of equipment failure or deviation of the process from specification, procedures shall be in place to establish the safety status and quality of the product to determine the action to be taken.	N/A
6.1.6	Documented checks of the production line shall be carried out before commencing production and following changes of product. These shall ensure that lines have been suitably cleaned and are ready for production. Documented checks shall be carried out at product changes to ensure all products and packaging from the previous production has been removed from the line before changing to the next production.	N/A

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GLOBAL STANDARD FOR FOOD SAFETY

6.1.7	Documented procedures shall be in place to ensure that products are packed into the correct packaging and correctly labelled. These shall include checks at the start of packing, during the packaging run, following packaging changes and when changing batches of packaging materials, in order to ensure that correct packaging materials are used. The procedures shall also include verification of any code information or other printing carried out at the packing stage.	N/A

6.2 Quantity-weight, volume and number control

The site operated a quantity control system, which conformed to legal requirements in the USA and any additional industry sector codes or specified customer requirements. Packaged products were weighed by QA every hour. Repacked products were packed by count and weights were verified hourly by QA.

Statement of Intent	**The company shall operate a quantity control system which conforms to legal requirements in the country where the product is sold and any additional industry sector codes or specified customer requirement.**	Y
6.2.1	The frequency and methodology of quantity checking shall meet the requirements of appropriate legislation governing quantity verification, and records of checks shall be maintained.	Y
6.2.2	Where the quantity of the product is not governed by legislative requirements (e.g. bulk quantity), the product must conform to customer requirements and records shall be maintained.	Y

6.3 Calibration and control of measuring and monitoring devices

The facility was able to demonstrate that measuring and monitoring equipment was sufficiently accurate and reliable to provide confidence in measurement results . A list of equipment requiring calibration, location, and due date, was held.

The Calibration procedure 8.6.1 was reviewed. The procedure included metal detectors, thermometers, scales, free chlorine meter, pH meters, oxygen meter and pipettes.

Metal detectors were checked hourly as well as calibrated annually by Fortress Technology. Last calibration was completed on March 09, 2015.

The hand held thermometers, pH meters and ORP probes are replaced often due to cost of replacement versus the cost of calibration.

Scales were calibrated monthly by C.C. Vaughn, but checked daily using certificated check weights. In the event of a calibration failure, the item involved is withdrawn from service. Bagging Scales are certified monthly by the maintenance department.

Oxygen meters are sent to the manufacturer annually for calibration and checked daily against an air sample. Last calibration was conducted by Bridge Analizer Inc on Feb 1,2015. Pippettes are checked daily of before use.

Free chlorine meters were calibrated each time they were used by QA.

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Statement of Intent	**The company shall be able to demonstrate that measuring and monitoring equipment is sufficiently accurate and reliable to provide confidence in measurement results.**	Y
6.3.1	The company shall identify and control measuring equipment used to monitor CCPs, product safety and legality. This shall include as a minimum: • a documented list of equipment and its location • an identification code and calibration due date • prevention from adjustment by unauthorised staff • protection from damage, deterioration or misuse.	Y
6.3.2	All identified measuring devices, including new equipment, shall be checked and where necessary adjusted: • at a predetermined frequency, based on risk assessment • to a defined method traceable to a recognised national or international Standard where possible. Results shall be documented. Equipment shall be readable and be of a suitable accuracy for the measurements it is required to perform.	Y
6.3.3	Reference measuring equipment shall be calibrated and traceable to a recognised national or international Standard and records maintained.	Y
6.3.4	Procedures shall be in place to record actions to be taken when the prescribed measuring and monitoring devices are found not to be operating within specified limits. Where the safety or legality of products is based on equipment found to be inaccurate, action shall to be taken to ensure at-risk product is not offered for sale.	Y

7 PERSONNEL

The facility has a training program in place that consists of orientation training, training that is targeted to specific positions or jobs, and annual refresher training. Training was tracked and managed through the Alchemy training system.

Quizzes confirmed competency post training. The training program included: the necessary competencies for specific roles, provided training or tests to ensure staff had the necessary competencies, reviewed the effectiveness of training and the delivery of training was in the appropriate language of trainees. Training records included: name of the trainee, date, title of the course and name of the trainer.

Personnel verifying CCP devices had training in October 2014.

Twelve individuals were interviewed during the audit, and all were able to explain their responsibilities and job duties; they explained

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what to do if there was a food safety or quality issue and they were all able to give examples of GMPs. Evidence of training in food safety topics at orientation was requested for two new employees selected randomly, and found to have received the orientation training. In addition training records were reviewed for Amanda J. shipping, Sam L. and Rebecca G. QA Technician and were found to be complete. Temporary workers received the same training as staff. Training records are held by the HR Manager.		
FUNDAMENTAL Statement of Intent	**The company shall ensure that all personnel performing work that affects product safety, legality and quality are demonstrably competent to carry out their activity, through training, work experience or qualification.**	Y
7.1.1	All relevant personnel, including temporary staff and contractors, shall be appropriately trained prior to commencing work and adequately supervised throughout the working period.	Y
7.1.2	Where personnel are engaged in activities relating to critical control points, relevant training and competency assessment shall be in place.	Y
7.1.3	The company shall put in place documented programmes covering the training needs of relevant personnel. These shall include as a minimum: • identifying the necessary competencies for specific roles • providing training or other action to ensure staff have the necessary competencies • reviewing the effectiveness of training • the delivery of training in the appropriate language of trainees.	Y
7.1.4	Records of all training shall be available. This shall include as a minimum: • the name of the trainee and confirmation of attendance • the date and duration of the training • the title or course contents, as appropriate • the training provider. Where training is undertaken by agencies on behalf of the company, records of the training shall be available.	Y
7.1.5	The company shall routinely review the competencies of its staff. As appropriate, it shall provide relevant training. This may be in the form of training, refresher training, coaching, mentoring or on-the-job experience.	Y
7.2	**Personal hygiene. Raw material handling, preparation, processing,**	

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The Good Manufacturing Practices guidelines 1.9 dated April 29, 2013 cover all aspects of GMPs and are communicated to employees during orientation, and refresher training. It addressed the following areas: infectious diseases, injuries, first aid, metal detectable bandage, medication, personal practices, hand washing and sanitizing, fingernails, gloves, hair restraints, smocks, clothing, footwear, jewelry, fragrances, personal items, food and beverages, smoking and tobacco.

Watches were not worn, jewelry was not worn, with the exception of a plain wedding ring, rings and studs in exposed parts of the body, such as ears, noses, tongues and eyebrows were not worn, fingernails were kept short, clean and unvarnished, false fingernails were not permitted, and excessive perfume or aftershave were not permitted.

Visitor and contractor acknowledgement that they understand the GMPs is required prior to entry into the facility.

Personal hygiene was monitored through regular hygiene audits.

Blue metal detectable plasters were use in the plant. Each new delivery of plasters was checked through metal detectors to ensure detection.

Statement of Intent		**The company's personal hygiene standards shall be appropriate to the products produced, documented, and adopted by all personnel, including agency staff, contractors and visitors to the production facility.**	Y
7.2.1		The requirements for personal hygiene shall be documented and communicated to all personnel. This shall include as a minimum the following requirements: • Watches shall not be worn. • Jewellery shall not be worn, with the exception of a plain wedding ring or wedding wristband. • Rings and studs in exposed parts of the body, such as ears, noses, tongues and eyebrows, shall not be worn. • Fingernails shall be kept short, clean and unvarnished. False fingernails shall not be permitted. • Excessive perfume or aftershave shall not be worn. Compliance with the requirements shall be checked routinely.	Y
7.2.2		Hand cleaning shall be performed on entry to the production areas and at a frequency that is appropriate to minimise the risk of product contamination.	Y
7.2.3		All cuts and grazes on exposed skin shall be covered by an appropriately coloured plaster that is different from the product colour (preferably blue) and containing a metal detectable strip. These shall be company issued and monitored. Where appropriate, in addition to the plaster, a glove shall be worn.	Y
7.2.4		Where metal detection equipment is used, a sample from each batch of plasters shall be successfully tested through the equipment and records shall be kept.	Y

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GLOBAL STANDARD FOR FOOD SAFETY

7.2.5	Processes and written instructions for staff shall be in place to control the use and storage of personal medicines, so as to minimise the risk of product contamination.	Y

7.3 Medical screening

Medical screening procedures are present for all employees. New employees are instructed during their orientation to report infectious disease condition(s). Plant employees with a suspected condition are not allowed to work in food processing areas and are referred to a doctor. All employees, visitors and contractors must sign a health questionnaire detailing the company's policy.

Statement of Intent	**The company shall ensure that procedures are in place to ensure that employees, agency staff, contractors or visitors are not a source of transmission of food-borne diseases to products.**	Y
7.3.1	The company shall have a procedure which enables notification by employees, including temporary employees, of any relevant infection, disease or condition with which they may have been in contact or be suffering from.	Y
7.3.2	Where there may be a risk to product safety, visitors and contractors shall be required to complete a health questionnaire or otherwise confirm that they are not suffering from a condition which may put product safety at risk, prior to entering the raw material, preparation, processing, packing and storage areas.	Y
7.3.3	There shall be documented procedures for employees, contractors and visitors, relating to action to be taken where they may be suffering from or have been in contact with an infectious disease. Expert medical advice shall be sought where required.	Y

7.4 Protective clothing Employees or visitors to production areas

Suitable company-issued protective clothing was worn by employees, contractors or visitors working in or entering production areas. Smocks (green – high care, blue- low risk), aprons, sleeve, gloves, and hairnets were provided to personnel to wear.

Protective clothing was provided in sufficient numbers for each employee, were of suitable design to prevent contamination of the product (no external pockets above the waist or buttons), fully contained all scalp hairnets to prevent product contamination, and included nets for beards where required to prevent product contamination.

Smocks and cutting gloves were laundered in-house daily. The Outer Garment Laundry Management procedure was reviewed. APC swabbing was performed on the smocks monthly to confirm the effectiveness of the laundering process.

All personnel wore blue disposable gloves. New gloves were worn when entering the production area or changing products. All protective clothing was laundered or disposed of.

7.4.6 is N/A because there are no non-launderable clothing items present.

One non conformity was raised against this section.

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Statement of Intent	**Suitable company-issued protective clothing shall be worn by employees, contractors or visitors working in or entering production areas.**	Y
7.4.1	The company shall document and communicate to all employees, contractors or visitors the rules regarding the wearing of protective clothing in specified work areas (e.g. high-care or low-risk areas). This shall also include policies relating to the wearing of protective clothing away from the production environment (e.g. removal before entering toilets, use of canteen and smoking areas).	N
7.4.2	Protective clothing shall be available that: • is provided in sufficient numbers for each employee • is of suitable design to prevent contamination of the product (as a minimum containing no external pockets above the waist or sewn on buttons) • fully contains all scalp hair to prevent product contamination • includes snoods for beards and moustaches where required to prevent product contamination.	Y
7.4.3	Laundering of protective clothing shall take place by an approved contracted or in-house laundry using defined and verified criteria to validate the effectiveness of the laundering process. Washing of workwear by the employee is exceptional but shall be acceptable where the protective clothing is to protect the employee from the products handled and the clothing is worn in enclosed product or low-risk areas only.	Y
7.4.4	Where protective clothing for high-care or high-risk areas is provided by a contracted laundry, this shall be audited either directly or by a third party, or should have a relevant certification. The laundry must operate procedures which ensure: • effective cleaning of the protective clothing • clothes are commercially sterile following the washing and drying process • adequate segregation between dirty and cleaned clothes • cleaned clothes are protected from contamination until delivered to the site, e.g. by the use of covers or bags.	Y
7.4.5	If gloves are used, they shall be replaced regularly. Where appropriate, gloves shall be suitable for food use, of a disposable type, of a distinctive colour (blue where possible), be intact and not shed loose fibres.	Y
7.4.6	Where items of personal protective clothing that are not suitable for laundering are provided (such as chain mail, gloves and aprons), these shall be cleaned and sanitised at a frequency based on risk.	N/A

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Good Manufacturing Practices

What are GMPs?

Good Manufacturing Practices

Legal regulations set in place to ensure that the food we produce is safe

Good Manufacturing Practices

GMPs are legal regulations set in place to ensure that the food we produce is safe and the highest quality possible.

Every employee has a moral, ethical and legal responsibilities to comply.

Remember -

The product you help prepare today, you or your family may consume tomorrow!

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GMP's: Personal Hygiene









- Employees should maintain a level of hygiene and personal cleanliness compatible with working in a food plant.
- Employee must shower daily and wear clean clothes.
- Use of heavy aftershave or perfume is not permitted in production areas

GMP Topics

- Food Defense/Food Security
- Sickness/Illness
- Personal Hygiene
- Work Practices
- Food Safety
- HACCP
- Sanitation
- Allergens



Food Defense/Food Security

- Protecting food and packaging from contamination with harmful intent









Food Defense/Food Security

- Why is food a target?





- Who would target food?

Terrorists, Criminals, Disgruntled employees

Food Defense/Food Security

Your Responsibilities

- Alert supervisor of any suspicions/ concerns
- Follow all company rules, policies, procedures
- Report instances of contamination (incidental or intentional)
- More ideas?



Any Questions?

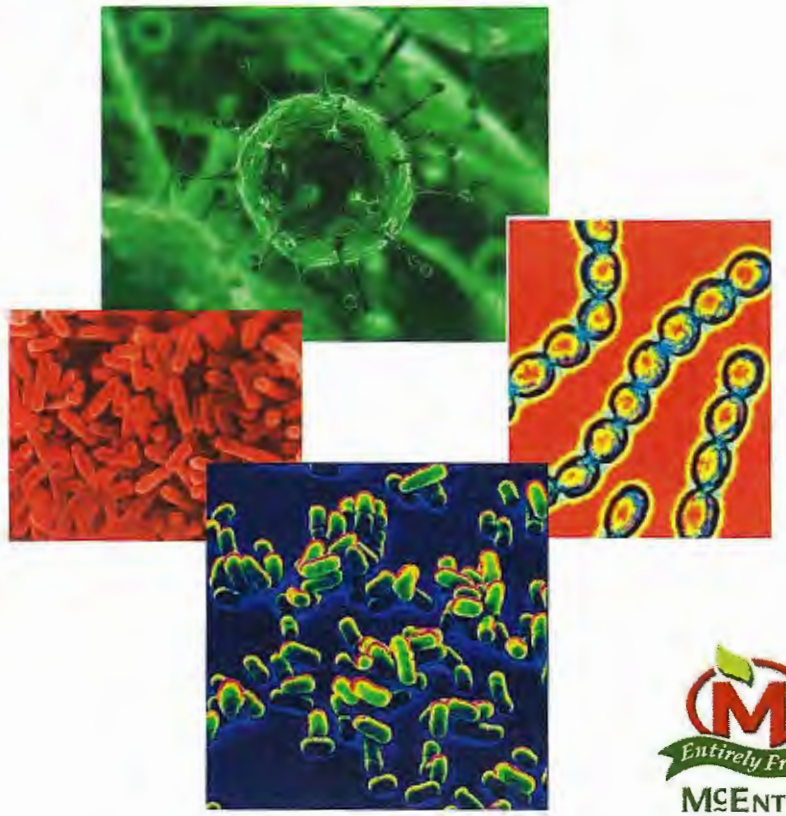
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GMP's: Sickness/Illness

These are symptoms for which you may want to consult with a physician.

Flu-like symptoms include:

- Body aches and pain
- Vomiting
- Diarrhea
- Infections
- Fever



If you get sick at work, tell your supervisor!

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GMP's: Sickness/Illness

- Salmonella
- E.Coli
- Shigella
- Hepatitis

Most commonly spread by infected food handlers! If you are contagious, do not work with food product! EVERYONE should always be on the lookout for sick employees!

GMP's: Sickness/Illness

Excessive and unexcused absences will not be tolerated and require disciplinary actions.

GMP's: Personal Hygiene

Expectations

- Good Personal Hygiene
- Good Food Handling Practices
- Clean and Sanitary Environment

GMP's: Sickness/Illness

- Employees with symptoms of diarrhea, fever, vomiting or other potential infection illnesses are restricted from working with or in the vicinity of food and/or food contact surfaces.
- No persons with obvious sores, infected wounds, or any other infection or communicable disease, including colds and viruses shall be permitted to contact
- **Doctor's excuses are required**

  for missed work



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GMP's: Personal Hygiene



Before Work

- Cover any cuts or sores with blue bandages from first-aid
- Remove jewelry, artificial nails, fingernail polish, and false eye-lashes







NOT OK!

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GMP's: Personal Hygiene



At Work (already have Hairnet and beardguard in place)

1. Put on boot covers
2. Wash hands with soap and hot water (20 seconds)
3. Put on smock
4. Put on gloves, sleeves, and apron
5. Put on helmet/hearing protection
6. Enter production room





GMP's: Personal Hygiene



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GMP's: Personal Hygiene

The following video depicts proper dress procedures and hand washing

Proper Dress Procedure

GMP's: Personal Hygiene

According to the **Center for Disease Control** hand washing is the single most important means of preventing foodborne illness.



GMP's: Personal Hygiene

Hands must be washed

before entering production area,

after using the restroom,

after eating, drinking, and smoking

Anytime hands become soiled or contaminated



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GMP's: Personal Hygiene

Hand Washing

- Use warmest water possible
- Use plenty of soap
- Scrub between fingers, nails, up to elbows
- Sing "Happy Birthday" twice (20 seconds)
- Dry using clean paper towel
- Throw towel into trash can



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GMP's: Personal Hygiene



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GMP's: Personal Hygiene

Always wash hands before putting on gloves.

Gloves must be sanitized when starting work and prior to working with exposed food or clean equipment and utensils.



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GMP's: Personal Hygiene

In Production

- Sneeze or cough in elbow
- Don't touch face
- Tell your supervisor you need to leave line
- Re-glove or sanitize glove after touching non-food grade items

GMP's: Personal Hygiene

- Do not wear smocks, gloves, shoulder sleeves into the restroom
- Do not lean on any machinery in the production area
- Every employee must wear a hard hat, hearing protection, smock, gloves, hairnet and beard guard when in the production area.

GMP's: Personal Hygiene



OK



NOT OK!





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ROA0949

GMP's: Personal Hygiene

Use automatic hygiene stations when entering processing room from hygiene room

OK



NOT OK!





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GMP's: HIGH Care

- Hair/beard net
- Boot Covers
- Wash Hands
- Green Smock
- Gloves
- Sleeve guards if handling product
- Apron if handling product
- Enter through automatic boot wash/hand sanitizer system



GMP's: LOW Care

Recycling, Shipping, Receiving forklift drivers



Hair/beard net

Wash Hands in low care hygiene room

Gloves

Mezzanine, Packout, A Area, and QA (MATERIAL HANDLERS)

OK

Hair/beard net

Wash Hands in low care hygiene room

Blue Smock

Gloves



Tomato Repack

Hair/beard net

Wash Hands in low care hygiene room

Gloves



Disposable aprons (as needed)

Sleeve covers (as needed)

Use sanitizing station up on entering Tomato Repack Room

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Plant Access



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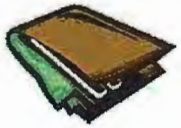
ROA0953

GMP's: Allowed Items

- **A wedding band without any set stones**
  - Must be covered by gloves
- **Medical alert bracelets**
  - Must be covered by gloves
- **Medication**
  - Must be approved by Safety Manager
- **Car Keys**
- **Wallet** – with change secured
- **Company identification card**
- **Company issued items** (cellphones and pens/pencils)
  - Must be stored below the waist






GMP's: Prohibited Items

- Food
- Cell phones
- Jewelry/watches
- Artificial finger nails, nail polish
- Fake eyelashes
- Tobacco
- Glass
- Non company issue knives

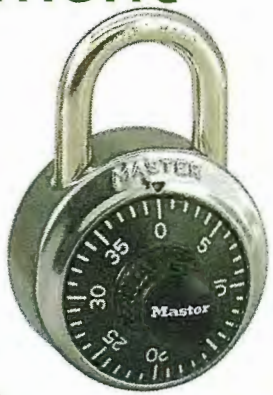




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GMP's: Lockers

- No food
- No wet, dirty clothes
- Must use company-provided lock
- Subject to inspection by management at anytime without notice



- Jackets, hats, wallets, jewelry, phones, cigarettes, lighters...etc.

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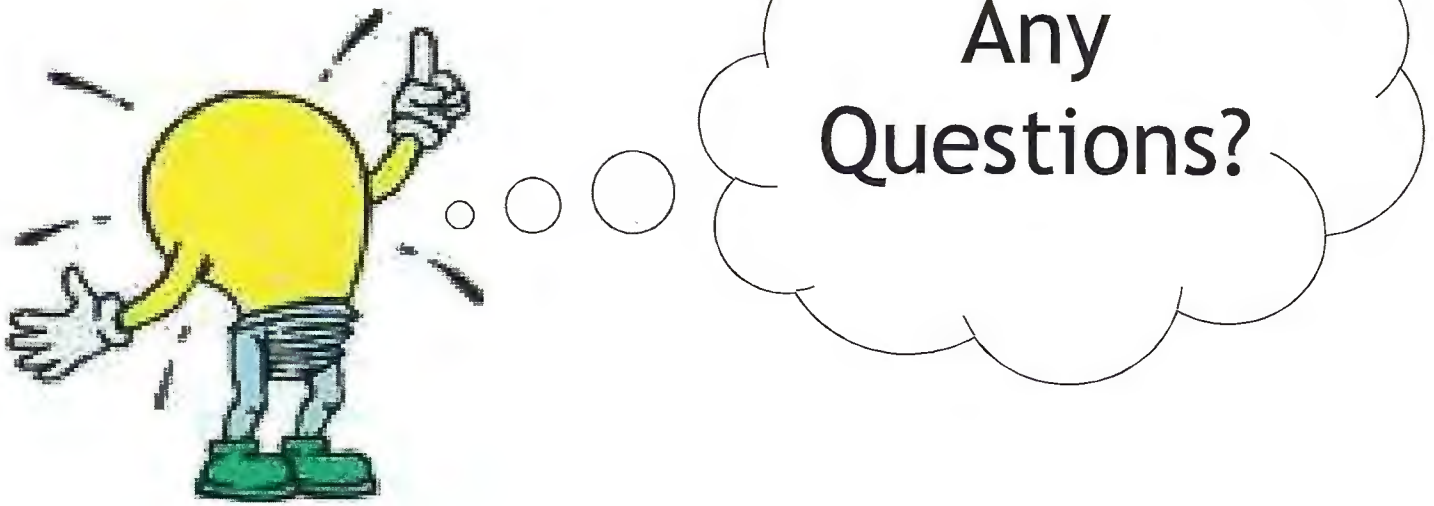
Breakroom/Vending

- Store lunches in refrigerators
- Buy snacks, drinks
- Don't store open cups in refrigerators
- NO FOOD BEYOND BREAKROOM





Entirely Fresh
McENTIRE PRODUCE™



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ROA0958

Work Practices



Entirely Fresh
McENTIRE PRODUCE™

ROA0959

Food Contact vs. Non-Food Contact

Food Contact

- Blue/Gray/White/ Yellow totes
- White handle knives
- Stainless steel shovels and stainless steel utensils

Non-Food Contact

- Red/Black totes
- Plastic shovels
- Plastic poles
- Plastic
- Floor

Food Contact vs. Non-Food Contact

- Don't store items on the floor
- Don't store packaging on the floor
- Don't put air hose or water hose nozzles on floor
- Use pallets
- Items that touch floor must be re-sanitized

OK



NOT OK!



HACCP

Is a systematic approach to food safety that addresses physical, chemical, and biological hazards as a means of prevention.

- H – Hazard
- A – Analysis
- C – Critical
- C – Control
- P - Point

HACCP

What it means to you...

Physical	Chemical*	Biological*
•Debris •Wood •Metal •Rocks	•Sodium hypochlorite •Cleaners	•Bacteria •Infection •Blood

If you suspect anything has contaminated the food, TELL YOUR SUPERVISOR!

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HACCP

CCP #1 - Water Sanitizer chemical Sodium Hypochlorite

Sanitizer used to treat the wash water used for the product.

- Flumes
- Dip tanks

CCP #2 - Metal Detector

Devices used to check finished product for metal.

- Machine parts
- Knives/blades

Metal Detectors

Only QA and Management are allowed to remove products rejected by metal detectors



OK



NOT OK!

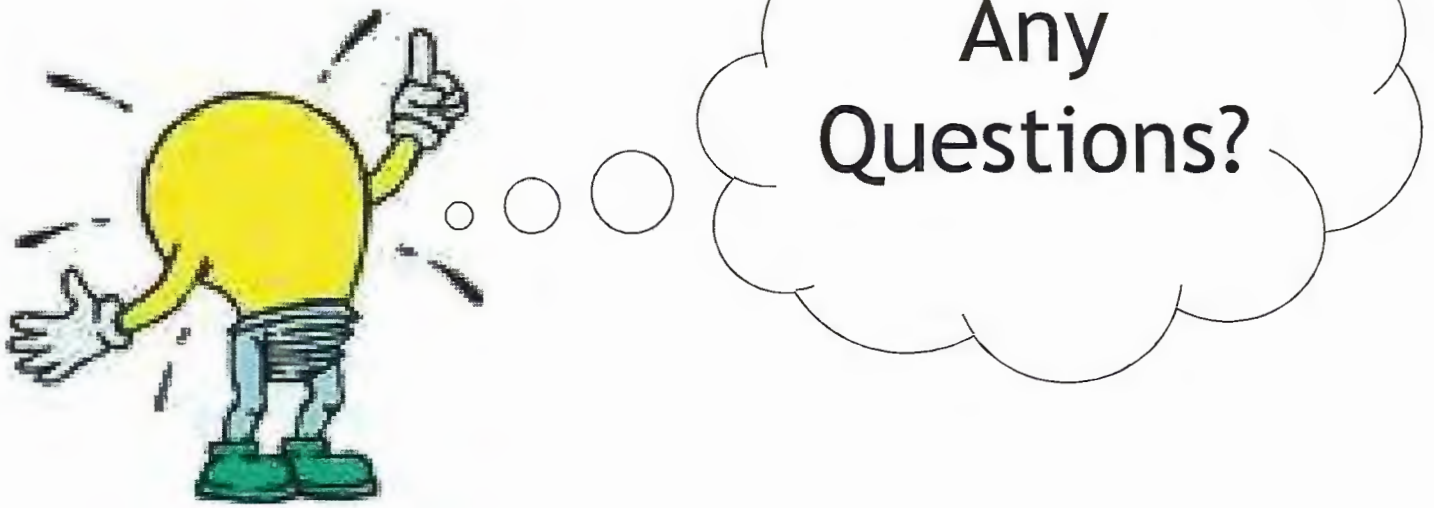
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Disposition Labels

Tampering with, or moving, tags from product placed on QA hold will result in termination.

QA HOLD

Entirely Fresh
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Entirely Fresh
McENTIRE
PRODUCE™

ROA0967

Sanitation

- No littering
- Dispose of trash properly
- No spitting
- Maintain 18” cleaning perimeter





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Plant Sanitation

- Inspect all equipment at startup for cleanliness
- Handle equipment properly when not in use





Entirely Fresh
McENTIRE PRODUCE™

Color Code

Containers

- Blue - Organic line
- White/Grey - Edible
- Red - inedible
- Black - Metal Detector rejects

Shovels

- Plastic - waste
- Stainless Steel - Edible

Knives

- White handles - Production

Gloves

- Blue - Production
- Purple - First Aid

Smocks

- Green - All Employees
- Garnet - Management/QA

Sanitation Scrub Brushes

- White or Blue Bristles - Food contact Surfaces
- Black or Red Bristles - Floor/Drains

Hard Hats

- White - McEntire Employees
- Yellow - Temp Employees
- Red - Maintenance
- Royal Blue - Quality Assurance
- Dark Blue - Managers/Supervisors
- Green - Visitors
- Orange - Mtl Handlers
- Gold - LCO

Entirely Fresh
McENTIRE PRODUCE™

Allergens

From the FDA:

Effective January 1, 2006, the Food and Drug Administration (FDA) is requiring food labels to clearly state if food products contain any ingredients that contain protein derived from the eight major allergenic foods. As a result of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), manufacturers are required to identify in plain English the presence of ingredients that contain protein derived from milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, or soybeans in the list of ingredients or to say "contains" followed by name of the source of the food allergen after or adjacent to the list of ingredients.

Entirely Fresh
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Allergen

Any new process or product brought into our facility will be reviewed using the Process Trials SOP and the Product Development form. The process or product will be reviewed by at least the VP of Operations and the Director of Quality Assurance for suitability and effective implementation following the Allergen Program. This is also included in our Red Folder Process.

Vending machines may contain allergens such as nuts, cheeses and milk. Lunches brought in by employees may contain items that are allergens.

Always wash and sanitize your hands after breaks and lunchtime before going back to the production floor.

Entirely Fresh
McENTIRE PRODUCE™

Allergen

If possible when the known allergen is a "part" of product such as a dressing it will be handled outside of the processing rooms. The pack out area and the staging area are the designated areas for product containing an allergen that is prepackaged. All of our allergens are prepackaged to mitigate any cross contamination issues.



Any Questions?

Entirely Fresh
McENTIRE PRODUCE™

ROA0974

Logan Mitchell

From: Logan Mitchell
Sent: Tuesday, July 19, 2016 9:51 AM
To: 'Dowl Knight, CPA'
Subject: RE: McEntire Audit

Mr. Knight,

Yes the document you signed to extend the limitation period did expire on May 31, 2016. Per S.C. Code section 12-54-85 the time limitation did not apply to this audit since the taxpayer had 20% understatement of the tax required to be shown on all periods under audit. The taxes in this case may be assessed at any time within 72 months from the date of the first period under audit. This is also stated at the bottom of the Explanation of Assessments which were part of the proposed notice of assessment email attachment.

Please let me know if you have any questions about the appeals process.

Thank you,

Logan Mitchell
Columbia District Auditor
(803)898-5908
mitchel@sctax.org

South Carolina Department of Revenue
Audit Services
Office of General Counsel Tax and Regulatory Division
300-A Outlet Point Blvd.
Columbia, SC 29210
dor.sc.gov

SOUTH CAROLINA
DOR
DEPARTMENT OF REVENUE

-----Original Message-----
From: Dowl Knight, CPA [mailto:dowl@adowlknightcpa.com]
Sent: Tuesday, July 19, 2016 9:30 AM
To: Logan Mitchell
Cc: 'Lance Ailshie'
Subject: RE: McEntire Audit

Good morning Logan,

This is the first assessment we have received. I believe that the Statue of Limitations has expired on a portion of the audit period. According to my records, I signed a document to extend the limitation period. That document expired on May 31, 2016.

Furthermore, we are disagreement with DOR's definition of the "manufacturing process" as it pertains to McEntire Produce, Inc. Wes and his manager referenced several cases during our discussions prior to Wes's resignation. In our opinion, none of those cases had facts and circumstances that pertain to a food produce processing process.

Please review the limitation period and make any immediate adjustments to the proposed assessment resulting from your review. We will then proceed with the necessary steps to appeal the assessment.

Thank you,

Dowl

From: Logan Mitchell [mailto:Logan.Mitchell@dor.sc.gov]
Sent: Tuesday, July 19, 2016 8:50 AM
To: Dowl Knight, CPA <dowl@adowlknightcpa.com>
Cc: 'Lance Ailshie' <lance.ailshie@mcentireproduce.com>
Subject: RE: McEntire Audit

Mr. Knight,

Attached is a copy of the use tax proposed assessment for McEntire Produce, Inc. covering the periods of 10/01/2012 - 9/30/2015. I have also attached a copy of Wes Butler's Excel spreadsheet with purchases held as subject to use tax. Please let me know if you have any questions or would like to schedule a conference to discuss the audit results.

Thank you,

Logan Mitchell

Columbia District Auditor

(803)898-5908

mitchel@sctax.org <mailto:mitchel@sctax.org>

South Carolina Department of Revenue

Audit Services

Office of General Counsel Tax and Regulatory Division

300-A Outlet Point Blvd.

Columbia, SC 29210

dor.sc.gov

SCDOR_Logo_FINAL

STATE OF SOUTH CAROLINA
DEPARTMENT OF REVENUE

CONSENT TO EXTEND TIME TO ASSESS TAX

FS-93
(Rev. 3/9/00)
2083

McEntire Produce Inc. — [redacted]
Name of Taxpayer(s) — File No.

2040 American Italian Way, Columbia, SC 29209-5084 — [redacted]
Address — SSN/FEI

and the SOUTH CAROLINA DEPARTMENT OF REVENUE previously entered into a written agreement that extended the time for mailing the notice of assessment or refund of any STATE Sales & Use tax due on any return(s) made by or for the period(s) ended 10/01/2012 through 09/30/2015 until 03/31/2016.

By executing this document the parties mutually agree to further extend the time for mailing the notice of assessment or refund of the above referenced tax for the period(s) ended 10/01/2012 through 09/30/2015 until 05/31/2016 in accordance with the provisions of Section 12-54-85(C)(5) of the 1976 South Carolina Code of Laws, as amended.

McEntire Produce Inc
(Name of Taxpayer)

By: [signature]
(Taxpayer, Partner, Corp. Officer, etc.)

POA — 3/23/16
(Title) — (Date)

SOUTH CAROLINA DEPARTMENT OF REVENUE

By: [signature]
(Administrator, Field Services Division) — 3/25/16 (Date)

If this waiver is executed on behalf of a corporation, it will be signed by such officer or officers of the corporation as are empowered under the laws of the State in which the corporation is located to sign for the corporation, in addition, to which the seal, if any, of the corporation must be affixed.

STATE OF SOUTH CAROLINA
DEPARTMENT OF REVENUE

CONSENT TO EXTEND TIME TO ASSESS TAX

FS-93
(Rev. 3/9/00)
2083

McEntire Produce Inc. — [redacted]
Name of Taxpayer(s) — File No.

2040 American Italian Way, Columbia, SC 29209-5084 — [redacted]
Address — SSN/FEI

and the SOUTH CAROLINA DEPARTMENT OF REVENUE previously entered into a written agreement that extended the time for mailing the notice of assessment or refund of any STATE Sales & Use tax due on any return(s) made by or for the period(s) ended 10/01/2012 through 09/30/2015 until 01/31/2016.

By executing this document the parties mutually agree to further extend the time for mailing the notice of assessment or refund of the above referenced tax for the period(s) ended 10/01/2012 through 09/30/2015 until 03/31/2016 in accordance with the provisions of Section 12-54-85(C)(5) of the 1976 South Carolina Code of Laws, as amended.

McEntire Produce, Inc
(Name of Taxpayer)

By: _____
(Taxpayer, Partner, Corp. Officer, etc.)

CFO; PAA
(Title)

1/20/2016
(Date)

SOUTH CAROLINA DEPARTMENT OF REVENUE

By: _____
(Administrator, Field Services Division)

1/20/2016
(Date)

If this waiver is executed on behalf of a corporation, it will be signed by such officer or officers of the corporation as are empowered under the laws of the State in which the corporation is located to sign for the corporation, in addition, to which the seal, if any, of the corporation must be affixed.

STATE OF SOUTH CAROLINA
DEPARTMENT OF REVENUE

CONSENT TO EXTEND THE TIME TO ASSESS TAX

FS-43
(Rev. 5/25/05)
2024

File No. [redacted]

McEntire Produce Inc. SSN/FEI [redacted]

Name of Taxpayer(s)

2040 American Italian Way, Columbia, SC 29209

Address (Number, Street, City or Town, State, Zip Code)

and the SOUTH CAROLINA DEPARTMENT OF REVENUE consent and agree to the following:

(1) The amount of any STATE Use tax due on any return(s) made by or for the above taxpayer(s) for the period(s) ended 10/1/2012 to 09/30/2015

may be assessed at any time on or before 01/31/2016
(Expiration Date)

This agreement extends the time for mailing the notice of assessment or refund of the above tax pursuant to the provisions of Section 12-54-85(C)(4) of the 1976 South Carolina Code of Laws, as amended.

McEntire Produce, Inc.
(Name of Taxpayer)

BY: [signature]
(Taxpayer, Partner, Officer of Corp., etc.)

POA
(Title)

11/3/2015
(Date)

SOUTH CAROLINA DEPARTMENT OF REVENUE

BY: [signature]
(Administrator, Field Services Division)

11/3/2015
(Date)

If this waiver is executed on behalf of a corporation, it will be signed by such officer or officers of the corporation as are empowered under the laws of the State in which the corporation is located to sign for the corporation.

1350

STATE OF SOUTH CAROLINA
DEPARTMENT OF REVENUE
Proposed Assessment

AS-6
(Rev. 09/23/15)
6376

File Number: 040439757
Letter ID: L0001633023
Date Issued: July 19, 2016

MCENTIRE PRODUCE INC
PO BOX 5817
COLUMBIA SC 29250-5817

Taxpayer:
A Sales & Use Audit of your South Carolina Sales and Use Tax return(s) from 10/01/2012 to 09/30/2015 has been conducted. Enclosed you will find an explanation of our **Proposed Assessment**. Below is a summary of our findings if paid by 08/18/2016:

Tax:	$126,912.90
Penalty:	$0.00
Interest:	$9,337.61
Total:	$136,250.51

Failure to respond to this notice by 10/17/2016 will result in the accrual of additional penalties and/or interest, and further collection action will be taken. Please refer to the reverse side for instructions on how to proceed. Should you have any questions, please do not hesitate to contact this office.

LOGAN MITCHELL, Field Audit
Email: Logan.Mitchell@dor.sc.gov, Phone: +1 (803) 898-5908, Fax: +1 (803) 896-0020
300A Outlet Pointe Blvd, Columbia, South Carolina 29210

This demand for payment is not applicable if you are currently in bankruptcy proceedings under Title 11 of the U.S. Code. Any monies due will be sought in accordance with the provisions of Title 11.

cut along dotted line

1350

SC DEPARTMENT OF REVENUE
Audit Payment

C-370
(Rev. 08/31/15)
6370

Pay online for free at MyDORWAY.dor.sc.gov.

Vouchers and payments may also be mailed to:

South Carolina Department of Revenue
P O Box 125
Columbia, SC 29214-0030

Media	136416686
File Number	040439757
Filing Period	09/30/2015
Amount Due	$136,250.51

Balance Remitted _____

637010151 01 000136416686 00 00 00000000 00013625051 6

If you agree with the changes detailed on this notice and any enclosed explanations, the balance should be remitted to this office within 30 days from the issue date of this letter to avoid additional penalties and interest, if applicable. To pay by check, please mail your payment **and the voucher** from the front page as addressed on the voucher to ensure proper processing.

If you agree with the Department's determination, but are unable to make full payment at this time, please complete the enclosed Waiver of Restriction on Assessment (SC870) and return it to this office as soon as possible. Upon receipt of this document, a final assessment will be issued.

You may agree with portions of the proposed assessment and disagree with others. The portion of the assessment with which you agree may be paid to avoid additional interest and penalty, and the remainder can be appealed.

If you disagree with part or all of the proposed assessment, you may make an appeal by sending a written protest within **90 days** from the date of this proposed assessment.

Protest forms (C-245) are available online at www.dor.sc.gov, by calling (803) 898-5320 or you may visit any South Carolina Department of Revenue office. You may choose to send a letter rather than using the Form C-245. The letter must contain the following information:

1. Taxpayer's name (individual, corporation, etc.)
2. Taxpayer's identification number (Social Security, Federal Employer Identification, License, etc.)
3. Period for which the tax is proposed
4. Type of tax in dispute (individual income, sales, etc.)
5. All of the reasons you disagree with the proposed assessment

If you have any questions, please call the telephone number shown on the front of this proposed assessment.

TAXPAYER'S BILL OF RIGHTS

- You have the right to apply for assistance from the Taxpayer Rights' Advocate within the Department of Revenue. The advocate or his designee is responsible for facilitating resolution of taxpayer complaints and problems.
- You have the right to request and receive forms, instructions and other written materials in plain, easy-to-understand language.
- You have the right to prompt, courteous service from us in all your dealings with the Department of Revenue.
- You have the right to request and receive written information guides, which explain in simple and nontechnical language, appeal procedures and your remedies as a taxpayer.
- You have the right to receive notices which contain descriptions of the basis for and identification of amounts of any tax, interest and penalties due.

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STATE OF SOUTH CAROLINA
DEPARTMENT OF REVENUE

Explanation of Audit Assessments and Adjustments

AS-21
(Rev. 08/23/15)
6391

File Number: 040439757
Letter ID: L0001531063
Date Issued: July 19, 2016

MCENTIRE PRODUCE INC
PO BOX 5817
COLUMBIA SC 29250-5817

The taxpayer's electronic purchase data was used to conduct the audit. Trial balances were provided by the taxpayer to verify the general ledger account balances. Various purchase invoices were selected for review by the auditor. Upon review, the taxpayer was found to have some use tax due during the audit period. The use tax due was on various non-processing related supplies and equipment purchased during the audit period. This included building supplies, hairnets, gloves, aprons, towels, cleaning supplies, storage containers and storage racks among other items. The taxpayer's electricity was held to be taxable at 10 percent of the total bill to account for electricity used in administrative and break areas as well as electricity used to cool raw material and finished goods storage areas.

FOR AN ADJUSTMENT TO USE TAX
A use tax is imposed on the storage, use, or other consumption in the State of tangible personal property purchased at retail for storage, use, or other consumption in this State, at the rate of five percent of the sales price of the property, regardless of whether the retailer is or is not engaged in business in this State.
SC Code Section 12-36-1310

Beginning June 1, 2007, an additional sales, use, and casual excise tax equal to one percent is imposed on amounts taxable pursuant to this chapter, except that this additional one percent tax does not apply to amounts taxed pursuant to:
_ Section 12-36-920(A) - accommodations for transients
_ Section 12-36-2110 - items subject to a maximum sales and use tax
_ Section 12-36-910(d)(1) - unprepared food which may be lawfully purchased with United States Department of Agriculture food coupons.
SC Code Section 12-36-1110

Every person storing, using, or otherwise consuming in this State tangible personal property purchased at retail, is liable for the use tax, until the tax is paid to the state.
SC Code Section 12-36-1330

LOCAL SALES & USE TAX
Counties may levy sales and use tax upon referendum approval. Such taxes are to be administered and collected by the SC Department of Revenue in the manner that sales and use taxes are administered and collected pursuant to Chapter 36 of Title 12. For more detailed information refer to SC Information Letter 05-1 of January 6, 2005 and Chapter 10 of Title 4.

INTEREST
Interest on taxes owed and refunds due is computed using the Internal Revenue Service interest rates <*> for underpayment compounded daily. Generally, interest is not paid during the first seventy-five days after filing a request for refund. SC Code Section 12-54-25

EXCEPTION TO TIME LIMITATION FOR ASSESSMENT OF TAXES
Per S.C. Code section 12-54-85, the time limitation did not apply to this audit since the taxpayer had 20% understatement of the total of tax required to be shown on all periods under audit. The taxes in this case may be assessed at any time within 72 months from the date of the first period under audit

1350

STATE OF SOUTH CAROLINA
DEPARTMENT OF REVENUE

Explanation of Audit Assessments and Adjustments

AS-21
(Rev. 08/23/15)
6391

File Number: 040439757
Letter ID: L0001531063
Date Issued: July 19, 2016

MCENTIRE PRODUCE INC
PO BOX 5817
COLUMBIA SC 29250-5817

LOGAN MITCHELL, Field Audit
Email: Logan.Mitchell@dor.sc.gov, Phone: +1 (803) 898-5908, Fax: +1 (803) 896-0020
300A Outlet Pointe Blvd, Columbia, South Carolina 29210

1350

Issued:
07/19/16

STATE OF SOUTH CAROLINA
DEPARTMENT OF REVENUE
Sales Working Paper Packet

AS-14
(Rev. 10/13/15)
6384

Sales Audit Period Summary

File Number	Period	Tax	Penalty	Interest	Total
040439757	10/31/2012	$1,718.16	$0.00	$212.11	$1,930.27
040439757	11/30/2012	$2,335.69	$0.00	$281.88	$2,617.57
040439757	12/31/2012	$1,845.03	$0.00	$217.52	$2,062.55
040439757	01/31/2013	$3,678.58	$0.00	$423.00	$4,101.58
040439757	02/28/2013	$2,327.37	$0.00	$261.66	$2,589.03
040439757	03/31/2013	$2,401.90	$0.00	$263.38	$2,665.28
040439757	04/30/2013	$2,869.79	$0.00	$306.67	$3,176.46
040439757	05/31/2013	$3,628.22	$0.00	$377.50	$4,005.72
040439757	06/30/2013	$7,656.41	$0.00	$776.27	$8,432.68
040439757	07/31/2013	$3,658.88	$0.00	$360.49	$4,019.37
040439757	08/31/2013	$3,173.22	$0.00	$303.77	$3,476.99
040439757	09/30/2013	$5,261.65	$0.00	$489.71	$5,751.36
040439757	10/31/2013	$3,331.38	$0.00	$300.66	$3,632.04
040439757	11/30/2013	$2,298.54	$0.00	$201.27	$2,499.81
040439757	12/31/2013	$2,059.98	$0.00	$174.74	$2,234.72
040439757	01/31/2014	$2,660.22	$0.00	$218.24	$2,878.46
040439757	02/28/2014	$2,088.66	$0.00	$166.15	$2,254.81
040439757	03/31/2014	$2,963.93	$0.00	$227.73	$3,191.66
040439757	04/30/2014	$3,522.41	$0.00	$261.19	$3,783.60
040439757	05/31/2014	$3,974.00	$0.00	$283.82	$4,257.82
040439757	06/30/2014	$3,338.31	$0.00	$229.71	$3,568.02
040439757	07/31/2014	$5,794.89	$0.00	$382.81	$6,177.70
040439757	08/31/2014	$5,897.30	$0.00	$373.92	$6,271.22
040439757	09/30/2014	$4,407.35	$0.00	$267.65	$4,675.00
040439757	10/31/2014	$5,951.11	$0.00	$345.34	$6,296.45
040439757	11/30/2014	$5,613.67	$0.00	$311.50	$5,925.17
040439757	12/31/2014	$2,210.93	$0.00	$116.60	$2,327.53
040439757	01/31/2015	$3,547.68	$0.00	$177.60	$3,725.28
040439757	02/28/2015	$2,902.53	$0.00	$138.29	$3,040.82
040439757	03/31/2015	$4,106.21	$0.00	$184.70	$4,290.91
040439757	04/30/2015	$2,741.02	$0.00	$119.72	$2,860.74
040439757	05/31/2015	$2,484.38	$0.00	$98.91	$2,583.29
040439757	06/30/2015	$2,332.14	$0.00	$86.74	$2,418.88
040439757	07/31/2015	$6,126.54	$0.00	$211.70	$6,338.24
040439757	08/31/2015	$3,205.05	$0.00	$102.40	$3,307.45
040439757	09/30/2015	$2,799.77	$0.00	$82.26	$2,882.03
		$126,912.90	**$0.00**	**$9,337.61**	**$136,250.51**

This is the final proposed assessment.

1350

Issued:
07/19/16

STATE OF SOUTH CAROLINA
DEPARTMENT OF REVENUE
Sales Working Paper Packet

AS-14
(Rev. 10/13/15)
6384

Sales Adjustments Summary

File Number	Period	Gross Reported	Sales Audited	Use Audited	Deductions Reported	Deductions Audited
040439757	10/31/2012	$6,637,167.00	$0.00	$24,545.12	$6,637,167.00	$0.00
040439757	11/30/2012	$5,834,717.00	$0.00	$33,366.93	$5,834,717.00	$0.00
040439757	12/31/2012	$5,697,829.00	$0.00	$26,357.54	$5,697,829.00	$0.00
040439757	01/31/2013	$6,564,658.00	$0.00	$52,551.24	$6,564,658.00	$0.00
040439757	02/28/2013	$5,269,778.00	$0.00	$33,248.09	$5,269,778.00	$0.00
040439757	03/31/2013	$6,221,129.00	$0.00	$34,312.78	$6,221,129.00	$0.00
040439757	04/30/2013	$8,695,380.00	$0.00	$40,996.96	$8,695,380.00	$0.00
040439757	05/31/2013	$10,768,403.00	$0.00	$45,352.73	$10,768,403.00	$0.00
040439757	06/30/2013	$10,206,094.00	$0.00	$95,705.13	$10,206,094.00	$0.00
040439757	07/31/2013	$11,164,843.00	$0.00	$45,735.98	$11,164,843.00	$0.00
040439757	08/31/2013	$9,232,487.00	$0.00	$39,665.26	$9,232,487.00	$0.00
040439757	09/30/2013	$9,495,828.00	$0.00	$65,800.46	$9,495,828.00	$0.00
040439757	10/31/2013	$8,978,389.00	$0.00	$41,642.41	$8,978,389.00	$0.00
040439757	11/30/2013	$7,405,168.00	$0.00	$28,731.72	$7,405,168.00	$0.00
040439757	12/31/2013	$7,623,425.00	$0.00	$25,749.63	$7,623,425.00	$0.00
040439757	01/31/2014	$7,884,130.00	$0.00	$33,252.66	$7,884,130.00	$0.00
040439757	02/28/2014	$7,370,178.00	$0.00	$26,108.37	$7,370,178.00	$0.00
040439757	03/31/2014	$7,375,674.00	$0.00	$37,049.15	$7,375,674.00	$0.00
040439757	04/30/2014	$9,292,433.00	$0.00	$44,030.24	$9,292,433.00	$0.00
040439757	05/31/2014	$9,038,459.00	$0.00	$49,674.99	$9,038,459.00	$0.00
040439757	06/30/2014	$7,719,301.00	$0.00	$41,728.91	$7,719,301.00	$0.00
040439757	07/31/2014	$9,192,991.00	$0.00	$72,436.10	$9,192,991.00	$0.00
040439757	08/31/2014	$7,987,591.00	$0.00	$73,716.35	$7,987,591.00	$0.00
040439757	09/30/2014	$7,452,392.00	$0.00	$55,091.83	$7,452,392.00	$0.00
040439757	10/31/2014	$8,890,739.00	$0.00	$74,388.80	$8,890,739.00	$0.00
040439757	11/30/2014	$6,432,940.00	$0.00	$70,197.81	$6,432,940.00	$0.00
040439757	12/31/2014	$8,220,814.00	$0.00	$27,636.51	$8,220,814.00	$0.00
040439757	01/31/2015	$7,775,034.00	$0.00	$44,346.01	$7,775,034.00	$0.00
040439757	02/28/2015	$7,678,843.00	$0.00	$36,281.57	$7,678,843.00	$0.00
040439757	03/31/2015	$8,539,211.00	$0.00	$51,327.58	$8,539,211.00	$0.00
040439757	04/30/2015	$10,055,900.00	$0.00	$42,462.75	$10,047,700.00	$0.00
040439757	05/31/2015	$9,250,350.00	$0.00	$31,054.67	$9,250,350.00	$0.00
040439757	06/30/2015	$9,323,532.00	$0.00	$29,151.61	$9,323,532.00	$0.00
040439757	07/31/2015	$10,632,165.00	$0.00	$76,581.65	$10,632,165.00	$0.00
040439757	08/31/2015	$8,991,860.00	$0.00	$40,063.10	$8,991,860.00	$0.00
040439757	09/30/2015	$9,980,836.45	$0.00	$34,997.17	$9,980,836.45	$0.00
		$298,880,668.45	**$0.00**	**$1,625,339.80**	**$298,872,468.45**	**$0.00**

This is the final proposed assessment.

1350

Issued:
07/19/16

STATE OF SOUTH CAROLINA
DEPARTMENT OF REVENUE
Sales Working Paper Packet

AS-14
(Rev. 10/13/15)
6384

Sales Net Adjustments Summary

File Number	Period	Taxable Reported	Taxable Audited	Understatement
040439757	10/31/2012	$0.00	$24,545.12	$24,545.12
040439757	11/30/2012	$0.00	$33,366.93	$33,366.93
040439757	12/31/2012	$0.00	$26,357.54	$26,357.54
040439757	01/31/2013	$0.00	$52,551.24	$52,551.24
040439757	02/28/2013	$0.00	$33,248.09	$33,248.09
040439757	03/31/2013	$0.00	$34,312.78	$34,312.78
040439757	04/30/2013	$0.00	$40,996.96	$40,996.96
040439757	05/31/2013	$0.00	$45,352.73	$45,352.73
040439757	06/30/2013	$0.00	$95,705.13	$95,705.13
040439757	07/31/2013	$0.00	$45,735.98	$45,735.98
040439757	08/31/2013	$0.00	$39,665.26	$39,665.26
040439757	09/30/2013	$0.00	$65,800.46	$65,800.46
040439757	10/31/2013	$0.00	$41,642.41	$41,642.41
040439757	11/30/2013	$0.00	$28,731.72	$28,731.72
040439757	12/31/2013	$0.00	$25,749.63	$25,749.63
040439757	01/31/2014	$0.00	$33,252.66	$33,252.66
040439757	02/28/2014	$0.00	$26,108.37	$26,108.37
040439757	03/31/2014	$0.00	$37,049.15	$37,049.15
040439757	04/30/2014	$0.00	$44,030.24	$44,030.24
040439757	05/31/2014	$0.00	$49,674.99	$49,674.99
040439757	06/30/2014	$0.00	$41,728.91	$41,728.91
040439757	07/31/2014	$0.00	$72,436.10	$72,436.10
040439757	08/31/2014	$0.00	$73,716.35	$73,716.35
040439757	09/30/2014	$0.00	$55,091.83	$55,091.83
040439757	10/31/2014	$0.00	$74,388.80	$74,388.80
040439757	11/30/2014	$0.00	$70,197.81	$70,197.81
040439757	12/31/2014	$0.00	$27,636.51	$27,636.51
040439757	01/31/2015	$0.00	$44,346.01	$44,346.01
040439757	02/28/2015	$0.00	$36,281.57	$36,281.57
040439757	03/31/2015	$0.00	$51,327.58	$51,327.58
040439757	04/30/2015	$8,200.00	$42,462.75	$34,262.75
040439757	05/31/2015	$0.00	$31,054.67	$31,054.67
040439757	06/30/2015	$0.00	$29,151.61	$29,151.61
040439757	07/31/2015	$0.00	$76,581.65	$76,581.65
040439757	08/31/2015	$0.00	$40,063.10	$40,063.10
040439757	09/30/2015	$0.00	$34,997.17	$34,997.17
		$8,200.00	**$1,625,339.80**	**$1,617,139.80**

This is the final proposed assessment.

1350

STATE OF SOUTH CAROLINA
DEPARTMENT OF REVENUE

Waiver of Restrictions on Assessment/Collection

SC-870
(Rev. 12/06/04)
3309

File Number: 040439757
Letter ID: L0001547447
Date Issued: July 19, 2016

MCENTIRE PRODUCE INC
PO BOX 5817
COLUMBIA SC 29250-5817

Increase (Decrease) in Tax, Interest and Penalties:

Type of Tax: Sales and Use Ta)
Periods Covered: 10/01/2012 to 09/30/2015
Tax: $126,912.90
Penalty: $0.00
Interest: $9,337.61

This information was prepared by LOGAN MITCHELL. Telephone Number: +1 (803) 898-5908

PLEASE READ THE INSTRUCTIONS ON THE REVERSE SIDE

Consent to Assessment and Collection of Additional Tax or Acceptance of Overassessment:

I have read and understand the instructions on the reverse side. I consent to the assessment and collection of any additional tax and penalties or accept any decrease in tax and penalties shown above, plus any interest provided by law. I understand that by signing this waiver, I consent to the above determination amounts(s) and must pay the additional amounts prior to contesting this matter any further.

Taxpayer's Signature: _____ Date: _____

Spouse's Signature: _____ Date: _____

Corporation Name (if applicable): _____

Signature: _____ Title: _____ Date: _____

GENERAL INFORMATION AND INSTRUCTIONS
SC870 (Rev. 12/6/04)

IMPORTANT: By signing this form, the taxpayer (1) agrees to pay the tax, interest, and penalties stated to be due; and (2) gives up the right to appeal this matter further. Interest and applicable penalties will continue to accrue until the balance due the Department is paid in full. Signing this form does **not** affect your right to file a claim for refund and does not prevent the Department from assessing additional tax found to be due at a later date.
NOTE: If you wish to give up your right to file a claim for refund and prevent the Department from assessing additional amounts at a later date, a SC870AD should be executed in lieu of this SC870.

CLAIM FOR

Executing this document does not prevent you from seeking a refund of State taxes paid. The refund claim must be filed within three years from the date the return was filed, or two years from the date of payment of the tax, whichever is later. See the SC Information Guide about the claim for refund procedure for additional information.

EXECUTING THIS

If this waiver relates to a joint individual income tax return, both husband and wife must sign the waiver.

If the SC870 is executed on behalf of a corporation, the waiver must include the corporation's name as well as the signature and title of the corporate officer executing this document.

If this waiver is associated with an income tax examination of a partnership or "S" corporation, each partner or shareholder must execute a separate form.

If this waiver is signed by someone acting in a fiduciary capacity (e.g. a personal administrator or trustee), Internal Revenue Service Form 56, Notice Concerning Fiduciary Relationship, must accompany this form unless previously provided.

An attorney, CPA or other agent may execute this form on behalf of a client provided such authority is granted in a power of attorney. The power of attorney must accompany this form unless previously provided.

GENERAL

We have an agreement with the Internal Revenue Service which provides for the exchange of tax information. If this change affects returns filed with the Internal Revenue Service, amended federal return(s) may need to be filed.

If you have any questions about this waiver, please contact the preparer.

McENTIRE PRODUCE, INC.
PO BOX 5817
COLUMBIA, SC 29250-5817

July 26, 2016

SC Department of Revenue
Attn: Logan Mitchell – Field Audit
300A Outlet Pointe Blvd.
Columbia, SC 29210

Re: File No. 040439757; EIN 57-0868353
Sales Tax; Tax Period 10-1-12 through
9-30-2015

Dear Ms. Mitchell:

I am in receipt of your notice of proposed assessment dated July 19, 2016. I have enclosed a copy for your reference. Please allow this letter to serve as a formal protest to the proposed assessment. Please also allow this letter to serve as a request for a conference to include myself, you, the SCDOR supervisor responsible for the audit work of Wes Butler (the former SCDOR auditor involved), and Mr. Lance Ailshie, CFO of the taxpayer. We would like to hold the conference at the taxpayer's facility in order for you and the supervisor to tour the plant to gain more insight in to the taxpayer's manufacturing process.

I am protesting the proposed assessment of use tax on items which the Department of Revenue ("DOR") deems to be non-manufacturing items. The taxpayer and I believe the manufacturing process begins with the receipt of the raw product and continues until the finished product is loaded on a truck for shipping to a customer due to Federal safety standards of which the taxpayer must comply. Failure to comply with these standards would jeopardize the taxpayer's business as well as subject it to substantial penalties. Because food safety is paramount to the taxpayer's ability to operate, we believe all aspects of following the safety guidelines are a part of the manufacturing process.

I have enclosed herewith an email thread sent to you on July 19, 2016 and previously sent to Wes Butler on May 3, 2016. The email references a link to FDA standards and also directed Mr. Butler's attention to certain paragraphs pertaining to the necessity of the "Cleanliness" of workers and the facility, which involves the wearing of gloves, hairnets, aprons, etc. to protect against contamination of the produce while it is being processed. Mr. Butler never acknowledged or responded to this information that we provided.

We also disagree with the DOR's position that 10% of the electric bill is for non-manufacturing purposes. We believe that all areas where refrigeration is required are part of the manufacturing process because the FDA mandates that any areas where the raw product, product that is in process, and the finished product must be stored under conditions to protect against contamination and microbial growth. The FDA mandates that fresh-cut produce be stored in areas with a temperature of 41 degrees Fahrenheit or less. Because of this requirement, we believe that only 2% of the company's electric bill relates to non-manufacturing processes. We would like to see the DOR's substantiation for determining its 10% position when we have our conference.

The taxpayer is one of the leading providers of fresh cut produce located in the state of SC. We do not believe that the DOR auditors and supervisor fully understand the guidelines the taxpayer must follow regarding food safety and that the food safety requirements are an integral part of the manufacturing process. In my previous discussions with Wes Butler, he only presented me with facts and circumstances of court cases involving SC Department of Revenue manufacturing processes that have little relevance to the facts and circumstances of the manufacturing processes involving fresh-cut produce.

I look forward to our conference and am in hopes of a resolution to the issues involved in the audit.

Sincerely,
McEntire Produce, Inc.

A Dowl Knight, CPA, POA

NEXSEN|PRUET

Burnet R. Maybank, III
Member
Admitted in SC

September 23, 2016

Logan Mitchell
South Carolina Department of Revenue
300A Outlet Pointe Blvd.
Columbia, SC 29210

RE: McEntire Produce, Inc.
File No. 040439757
Sales Tax Audit – 10/1/12 through 9/30/15

Dear Ms. Mitchell:

Jim Rourke and I have been retained by the above-referenced taxpayer in relation to the above-referenced tax audit. A copy of our Power of Attorney is included under **Tab 1**. Note the taxpayer does not wish to revoke the Power of Attorney of its accountant, A. Dowl Knight. We understand the taxpayer previously filed a protest via letter on July 16, 2016; please consider this correspondence as a supplement to the previously-filed protest.

The following summarizes the taxpayer's position with respect to the exemptions available regarding refrigeration and protective clothing used in the taxpayer's manufacturing process. We look forward to working with you in an effort to resolve this matter.

I. Available Exemptions

a. Machine Exemption (12-36-2120(17))

Electricity used by manufacturers of tangible personal property for sale is exempt from the tax under Code Section 12-36-2120(19). Moreover, under S.C. Regs. § 117-302.4, electricity used to control plant atmosphere as to temperature and/or moisture content, in the quality control of tangible personal property being manufactured for sale, is also exempt from the tax. The Machine Exemption cited above provides the most substantive and useful analysis when determining the scope of the the manufacturing process.

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E BMaybank@nexsenpruet.com
Nexsen Pruet, LLC
Attorneys and Counselors at Law

The Machine Exemption exempts from sales tax the sale of "machines used in manufacturing . . . tangible personal property for sale." This statute defines "machines" to include:

> the parts of machines, attachments, and replacements used, or manufactured for use, on or in the operation of the machines and which (a) are necessary to the operation of the machines and are customarily so used, or (b) are necessary to comply with the order of an agency of the United States or of this State for the prevention or abatement of pollution of air, water, or noise that is caused or threatened by any machine used as provided in this section.

Id.

S.C. Regs. 117-302.5 provides additional guidance related to the applicability of the Machine Exemption to certain manufacturers. Subsection (B)(1) narrows those machines eligible for the exemption to those "*integral and necessary* to the manufacturing process," such that "the product being manufactured is being manufactured 'for sale'" (emphasis added). The regulations provide a three-part test to determine whether a machine is "integral and necessary" to the manufacturing process:

> (1) The machine is used at a manufacturing facility. . . . It does not apply to machines used at a facility whose purpose is retailing, wholesaling, distributing, or some other non-manufacturing purposes.
> (2) The machine is used in, and serves as an essential and indispensable component part of the manufacturing process, and is used on an ongoing and continuous basis during the manufacturing process. A machine is not part of the manufacturing process merely because it is integral and necessary to the manufacturer.
> (3) The machine must be substantially "used in manufacturing . . . tangible personal property for sale." The statute does not required that the machine be used exclusively for manufacturing; however, incidental manufacturing use will not qualify for the exemption. For purposes of the exemption, more than one-third of a machine's use in manufacturing is substantial.

S.C. Regs. § 117.302.5(B)(1).

Generally, states follow one of two distinct lines of authority when determining what qualifies as machinery used in manufacturing: (1) the Integrated Plant Concept or (2) the "Ohio Rule". *See generally* Hellerstein, State Taxation, at § 14.05. The more restrictive Ohio Rule defines "manufacturing" as "essentially a transformation or conversion of material or things into a different state or form from that in which they originally existed." *Nat'l Tube Co. v. Glander*, 105 N.E.2d 648, 650 (Ohio 1952). Only those assets which physically transform raw materials during the manufacturing process into a different form are eligible for the exemption. In other words, "the test is not whether the property is essential to the operation of the plant but whether it is an actual part of the process of manufacture." *Hawes v. Custom Canners, Inc.*, 173 S.E.2d 40 (Ga. Ct. App. 1970).

On the other hand, the Integrated Plant Concept is far less restrictive. As the name implies, machinery shall be eligible for the exemption if it performs an essential or indispensable function in the taxpayer's manufacturing operations, regardless of whether it actually causes a physical change. This test is derived from *Niagara Mohawk Power Corp. v. Wanamaker*, 286 A.D. 446 (N.Y. 1955). In finding that both coal handling and ash disposal equipment fell within the exemption (including the cranes and car dumper that unloaded incoming coal; conveyor belts that moved the coal to the boiler; crushers and sprayers that processed the coal; and slag lines that carried ash from the boiler), the *Niagara* court determined the relevant questions to be:

> (1) Is the disputed item necessary to production?
> (2) How close, physically and causally, is the disputed item to the finished product?
> (3) Does the disputed item operate harmoniously with the admittedly exempt machinery to make an integrated and synchronized system?

The court found that the crane and car dumper were as essential to production as the generator itself, since a serious breakdown in operation would quickly stop or impair the output of electricity. The court also noted that while some structures may not play as active a role as other parts, "activity is not the test of directness." Instead, "[t]he important thing is that all parts of the plant contribute, continuously and vitally, to production, and they are all integrated and harmonized."

In *Spring Industries, Inc. v. Department of Revenue*, 99-ALJ-17-0153-CC (1999), Chief Judge Kittrell acknowledged that Professor Walter Hellerstein, author

of the above-cited treatise on state taxation, testified that South Carolina is classified as an "integrated plant theory state." In an unpublished opinion, the court of appeals affirmed the finding. It noted that although the Department urged the court to "interpret the term 'machines used in manufacturing' to include only items that are part of a production line," this position was "inconsistent with the result in [*Hercules Contractors and Engineers, Inc. v. South Carolina Tax Commission*, 280 S.C. 426, 313 S.E.2d 300 (1984)] and the language in [§ 12-36-2120(17)] that only requires a machine to be 'used in manufacturing,' rather than 'used directly in manufacturing,' as the [Department] suggests." *S.C. Dep't of Rev. v. Springs Indus., Inc.*, 2003-UP-029 (Ct. App. 2003). Thus, South Carolina law provides that so long as the equipment in question performs an essential function in the taxpayer's manufacturing operations, it will qualify for the machine exemption to the sales tax.

In this case, the refrigeration both immediately before and after the actual processing of the fresh produce is absolutely integral to the overall processing/manufacturing process. Without that refrigeration, it would seriously impair the ability of the taxpayer to efficiently and safely prepare a finished product for sale and distribution. The refrigeration contributes, both "continuously and vitally, to production" and the assembly line production is surely "integrated and harmonized," as described in the Integrated Plant concept above.

Moreover, federal guidelines mandate the refrigeration. According to Section VIII, Part C, Item 3, of the Food and Drug Administration's Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables (enclosed under **Tab 2**), fresh–cut produce is recommended to be stored in areas with a temperature of less than or equal to 41 degrees Fahrenheit. The Food Safety Modernization Act of 2011, Section 117.93, provides even further mandates in that any "Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container". Additionally, 21 C.F.R. § 110.80(b) provides:

> (b) Manufacturing operations. (1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.
>
> (2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of

> food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, aw, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.
>
> (3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:
>
> > (i) Maintaining refrigerated foods at 45 deg. F (7.2 deg. C) or below as appropriate for the particular food involved.

Since keeping the temperature of this product must be done to prevent contamination of our product, and must be stored (by Congressional Act) in certain areas of plant to prevent cross-contamination (storage racks are the only viable option) then it is considered continuous, on-going and integral to the manufacturing process and therefore exempt. Even once the product is loaded onto our trucks, the 41 degree requirement must be met until it is ready to be sold inside a restaurant. Temperature recorders are required for refrigerated trucks to ensure that the product never went above this requirement at any time while in transit.

Based on the foregoing, the electricity used for refrigeration immediately before and after the literal processing of the produce should be exempt from tax under § 12-36-2120(19) because, consistent with the Machine Exemption, those activities are integral and necessary to the manufacturing process.

II. Protective Clothing for Class 100 Facility (12-26-2120(54))

The Proposed Assessment also assessed use tax on hairnets, gloves, aprons, towels, and other items related to maintaining the physical environment of the processing areas. The taxpayer believes these purchases should be exempt from tax based on the prevailing guidance.

S.C. Code Ann. § 12-36-2120(54) exempts from sales tax the clothing and other attire required for working in a Class 100 or better clean room environment, as defined in Federal Standard 209E. As you may know, Federal Standard 209E was cancelled in 2001 (see Notice of Cancellation filed by U.S. General Services Administration (GSA) enclosed under **Tab 3**). In its place, the governing body recommended, and the GSA adopted in its place ISA 14644-1.

"Class 100" describes the number and size of particles permitted per volume of air in "cleanroom" environments. Class 100 under Federal Standard 209E, which is equivalent to ISO 5, permits 100 particles of 0.5 microns or greater per cubic foot. As described in Section VII, Part B, Item 3 in **Tab 2**, the FDA recommends filtering compressed air that comes into contact with produce to be 0.3 microns.

Although the FDA-recommended environment should be filtered to 0.3 microns, the taxpayer filters its air to 0.1 microns. BRC Global Standards, an industry-leading safety and quality certification program, conducts an annual audit regarding the quality, safety and operational manufacturing standards. From its 2015 annual audit, BRC Global Standards concluded that the taxpayer's "[c]ompressed air used directly in contact with the product contact surfaces is filtered by a series of two filters (first filter 1 micron, second filter 0.1 micron)." This means any compressed air used by the taxpayer meets, and in fact exceeds, the "Class 100 or better" recommendation described by the exemption. The taxpayer's fresh-cut produce is handled in an environment that is applicable to a Class 100 environment, and thus all protective clothing used in that environment should be exempt under § 12-36-2120(54).

III. Pollution Control Exemption (§ 12-36-2120(17))

Finally, in the alternative, we believe the purchases deemed taxable in the Proposed Assessment are exempt under the Pollution Control Exemption provided in § 12-36-2120(17), which exempts all property that is "necessary to comply with the order of an agency of the United States or of this State for the prevention or abatement of pollution...." In this case, the purchases at issue are required by federal statute or regulation and protect against pollution through contamination of food. Specifically, 21 C.F.R. § 110.10 requires plant management to take all reasonable measures and precautions regarding the maintenance of a clean facility, including the following:

> (b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials **shall** conform to hygienic practices while on duty to the extent necessary to protect against contamination of food.

> The methods for maintaining cleanliness include, but are not limited to:
>
> > (1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or
> > ...
> > (3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
> > ...
> > (5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.
> > (6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(emphasis added).

Please take some time to review and let me know if you have any questions. We look forward to working with you.

Very truly yours,

Burnet R. Maybank, III

BRM/mw

Enclosures

cc: Rodger Watson
A. Dowl Knight (via electronic mail)
Carter McEntire (via electronic mail)



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STATE OF SOUTH CAROLINA
DEPARTMENT OF REVENUE

POWER OF ATTORNEY AND DECLARATION OF REPRESENTATIVE

SC2848
(Rev. 12/1/11)
3307

Part I Power of Attorney

1 Taxpayer Information (Note: Taxpayer(s) must sign and date this form on page 2, line 8.)

* Taxpayer name(s) and address **(Type or print.)**	* Social Security number(s)	* Employer identification number
McEntire Produce, Inc. PO Box 5817 Columbia, SC 29250-5817		57-0868353
		Plan number (if applicable)
	* Daytime telephone number ( )	Email Address

hereby appoint(s) the following representative(s) as attorney(s) - in fact:

2 Representative(s) (Type or print.)

* Name and address of specific individual	
Burnet R. Maybank III 1230 Main Street, Suite 700 Columbia, SC 29201	* Telephone No. (803) 540-2048 Fax No. (803) 727-1472 Check if new: Address ☐ Telephone No. ☐
Name and address of specific individual	
Jim Rourke 1230 Main Street, Suite 700 Columbia, SC 29201	Telephone No. (803) 540-2030 Fax No. (803) 727-1475 Check if new: Address ☐ Telephone No. ☐
Name and address of specific individual	
	Telephone No. ( ) Fax No. ( ) Check if new: Address ☐ Telephone No. ☐

to represent the taxpayer(s) before the SC Department of Revenue for the following tax matters:

3 Tax Matters - A general reference to "All years," "All periods," or "All taxes" is **not** acceptable.

* Type of Tax (Individual, Corporate, Withholding, Sales, etc.)	* Tax Form Number (SC1040, WH1605, ST-3, etc.)	* Year(s) or Period(s) (See Line 3 instructions)
Sales and Use Tax	ST-3	2012-2015

4 Acts Authorized - A representative is an individual authorized to receive and inspect confidential tax information and to perform any and all acts on behalf of the taxpayer with respect to the tax matters described in line 3, including the authority to sign any agreements, consents or other documents. You may not use a Power of Attorney form to authorize a representative to receive refund checks. You may authorize a representative to sign a return ONLY as set forth in South Carolina Code Section 12-2-75.

List any specific additions to or deletions from the acts otherwise authorized in this power of attorney: _____

_____

_____

5 Receipt of Refund Checks - If you want to authorize a representative named in line 2 to receive, **BUT NOT TO ENDORSE OR CASH** refund checks, initial here _____ and list the name of that representative below.

Name of representative to receive refund check(s) ▶ _____

6 **Retention/Revocation of Prior Power(s) of Attorney** - The filing of this power of attorney automatically revokes all earlier power(s) of attorney on file with the South Carolina Department of Revenue for the **same** tax matters for years or periods covered by this document.

If you do not want to revoke a prior power of attorney, check here ..... ▶ ☑

YOU MUST ATTACH A COPY OF ANY POWER OF ATTORNEY YOU WANT TO REMAIN IN EFFECT.

7 **Signature of Taxpayer(s)** - If a tax matter concerns a joint return, **both** husband and wife must sign if joint representation is requested; otherwise, see the instructions for SC2848 concerning signature of taxpayer(s). If signed by a corporate officer, partner, guardian, tax matters partner/person, LLC members, executor, receiver, personal representative, or trustee on behalf of the taxpayer, I certify that I have the authority to execute this form on behalf of the taxpayer.

▶ **The Department will not accept a Power of Attorney that is not signed.**

* _____ (Signature) * 9/20/16 (Date) President (Title (if applicable))

* Carter McEntire (Print Name)

_____ (Signature) _____ (Date) _____ (Title (if applicable))

_____ (Print Name)

NOTICES AND COMMUNICATIONS

All Notices and Communications will be sent to the taxpayer only. However, if you are unable to forward a copy to your named representative, you may contact our office for assistance.

Part II Declaration of Representative

I declare that:

- I am authorized to represent the taxpayer(s) identified in Part I for the tax matter(s) specified; and
- I am one of the following:
  - **a** Attorney - a member in good standing of the bar of the highest court of the jurisdiction shown below.
  - **b** Certified Public Accountant - duly qualified to practice as a certified public accountant in the jurisdiction shown below.
  - **c** Enrolled Agent - enrolled as an agent under the Requirements of the US Treasury Department Circular No. 230.
  - **d** Officer - a bona fide officer of the taxpayer organization.
  - **e** Full-Time Employee - a full-time employee of the taxpayer.
  - **f** Family Member - a member of the taxpayer's immediate family (i.e., spouse, parent, child, brother, or sister).
  - **g** Return Preparer.
  - **h** Other, please explain. _____

▶ **The Department will not accept a Declaration of Representative that is not signed.**

I declare that this return and all attachments are true, correct and complete to the best of my knowledge and belief. To wilfully furnish a false or fraudulent statement to the Department is a crime.

* Designation - Insert above letter (a-h)	* Jurisdiction (state)	* Signature	* Date
a	SC		9/20/16
a	SC		9-20-16

* indicates required field.

1350

STATE OF SOUTH CAROLINA
DEPARTMENT OF REVENUE

POWER OF ATTORNEY AND DECLARATION OF REPRESENTATIVE

SC2848
(Rev. 12/1/11)
3307

Part I Power of Attorney

1 Taxpayer Information (Note: Taxpayer(s) must sign and date this form on page 2, line 8.)

* Taxpayer name(s) and address (Type or print.)	* Social Security number(s)	* Employer identification number
McEntire Produce Inc PO Box 5817 Columbia, SC 29250-5817		57-0868353
		Plan number (if applicable)
	* Daytime telephone number (803) 799-3388	Email Address

hereby appoint(s) the following representative(s) as attorney(s) - in fact:

2 Representative(s) (Type or print.)

* Name and address of specific individual	
A. Dowl Knight, CPA 9357 Two Notch Rd, STE 101 Columbia, SC 29223-6400	* Telephone No. (803) 736-5500 Fax No. (803) 736-5501 Check if new: Address ☐ Telephone No. ☐
Name and address of specific individual	Telephone No. ( ) Fax No. ( ) Check if new: Address ☐ Telephone No. ☐
Name and address of specific individual	Telephone No. ( ) Fax No. ( ) Check if new: Address ☐ Telephone No. ☐

to represent the taxpayer(s) before the SC Department of Revenue for the following tax matters:

3 Tax Matters - A general reference to "All years," "All periods," or "All taxes" is not acceptable.

* Type of Tax (Individual, Corporate, Withholding, Sales, etc.)	* Tax Form Number (SC1040, WH1605, ST-3, etc.)	* Year(s) or Period(s) (See Line 3 instructions)
Sales Tax	ST-3, ST-389	9/2012-8/2015

4 Acts Authorized - A representative is an individual authorized to receive and inspect confidential tax information and to perform any and all acts on behalf of the taxpayer with respect to the tax matters described in line 3, including the authority to sign any agreements, consents or other documents. You may not use a Power of Attorney form to authorize a representative to receive refund checks. You may authorize a representative to sign a return ONLY as set forth in South Carolina Code Section 12-2-75.

List any specific additions to or deletions from the acts otherwise authorized in this power of attorney: _____

5 Receipt of Refund Checks - If you want to authorize a representative named in line 2 to receive, **BUT NOT TO ENDORSE OR CASH** refund checks, initial here _____ and list the name of that representative below.

Name of representative to receive refund check(s) ▶ _____

6 **Retention/Revocation of Prior Power(s) of Attorney** - The filing of this power of attorney automatically revokes all earlier power(s) of attorney on file with the South Carolina Department of Revenue for the same tax matters for years or periods covered by this document.

If you do not want to revoke a prior power of attorney, check here . . . . . ▶ ☐

YOU MUST ATTACH A COPY OF ANY POWER OF ATTORNEY YOU WANT TO REMAIN IN EFFECT.

7 **Signature of Taxpayer(s)** - If a tax matter concerns a joint return, **both** husband and wife must sign if joint representation is requested; otherwise, see the instructions for SC2848 concerning signature of taxpayer(s). If signed by a corporate officer, partner, guardian, tax matters partner/person, LLC members, executor, receiver, personal representative, or trustee on behalf of the taxpayer, I certify that I have the authority to execute this form on behalf of the taxpayer.

▶ **The Department will not accept a Power of Attorney that is not signed.**

Signature	Date	Title (if applicable)
*/ [signature]	*/ 9/23/15	/ President & CEO

*/ Carter McEntire
Print Name

Signature	Date	Title (if applicable)

Print Name

NOTICES AND COMMUNICATIONS

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* Designation - Insert above letter (a-h)	* Jurisdiction (state)	* Signature	* Date
b	SC		9/28/2015

* indicates required field.



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Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables

Contains Nonbinding Recommendations

February 2008

Additional copies are available from:
Office of Food Safety
Division of Plant and Dairy Food Safety (HFS-317)
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College Park, MD 20740
(Tel) 301-436-1700 (Updated phone: 240-402-1700)
http://www.cfsan.fda.gov/guidance.html

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
February 2008

OMB Control No. 0910-0609
Expiration Date: 10/31/2010
See additional PRA statement in section XIII of this guidance.

Contains Nonbinding Recommendations

Guidance for Industry

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Contains Nonbinding Recommendations

Guidance for Industry(1) Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables

Guidance

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

I. Introduction

The Federal Government provides advice on healthful eating, including consuming a diet rich in a variety of fruits and vegetables, through the *Dietary Guidelines for Americans* and the related MyPyramid food guidance system (Ref. 1, 2). In response, per capita consumption data show that Americans are eating more fresh produce (Ref. 3). With $12 billion in annual sales in the past few years (Ref. 4), the fresh-cut sector of the produce industry is its fastest growing segment. As the fresh-cut produce market continues to grow, the processors of such produce are faced with the challenge of processing an increasing variety and volume of products in a manner that ensures the safety of this produce. From 1996 to 2006, seventy-two foodborne illness outbreaks were associated with the consumption of fresh produce. Of these produce related outbreaks, 25 percent (18 outbreaks) implicated fresh-cut produce (Ref. 5). Many factors may play a role in the incidence and reporting of foodborne illness outbreaks that implicate fresh produce, such as an aging population that is susceptible to foodborne illness, an increase in global trade, a more complex supply chain, improved surveillance and detection of foodborne illness, improvements in epidemiological investigation, and increasingly better methods to identify pathogens (Refs. 6 thru 12).

Processing fresh produce into fresh-cut products increases the risk of bacterial growth and contamination by breaking the natural exterior barrier of the produce (Ref. 6).The release of plant cellular fluids when produce is chopped or shredded provides a nutritive medium in which pathogens, if present, can survive or grow (Ref. 6). Thus, if pathogens are present when the surface integrity of the fruit or vegetable is broken, pathogen growth can occur and contamination may spread. The processing of fresh produce without proper sanitation procedures in the processing environment increases the potential for contamination by pathogens (see Appendix B, "Foodborne Pathogens Associated with Fresh Fruits and Vegetables."). In addition, the degree of handling and product mixing common to many fresh-cut processing operations can provide opportunities for contamination and for spreading contamination through a large volume of product. The potential for pathogens to survive or grow is increased by the high moisture and nutrient content of fresh-cut fruits and vegetables, the absence of a lethal process (e.g., heat) during production to eliminate pathogens, and the potential for temperature abuse during processing, storage, transport, and retail display (Ref. 6). Importantly, however, fresh-cut produce processing has the capability to reduce the risk of contamination by placing the preparation of fresh-cut produce in a controlled, sanitary facility.

This guidance is intended for all fresh-cut produce processing firms, both domestic firms and firms importing or offering fresh-cut product for import into the U.S., to enhance the safety of fresh-cut produce by minimizing the microbial food safety hazards. This guidance does not set binding requirements or identify all possible preventive measures to minimize microbial food safety hazards. We recommend that each fresh-cut produce processor assess the recommendations in this guidance and then tailor its food safety practices to the processor's particular operation. Alternative approaches that minimize microbial food safety hazards may be used so long as they are consistent with applicable laws and regulations.

This guidance primarily addresses microbiological hazards and appropriate control measures for such hazards. However, some chapters in the guidance discuss physical and chemical hazards.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Scope and Use

Fresh-cut Produce: This guidance covers fresh-cut fruits and vegetables that have been minimally processed (e.g., no lethal kill step), and altered in form, by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing or other treatment, prior to being packaged for use by the consumer or a retail establishment. Examples of fresh-cut products are shredded lettuce, sliced tomatoes, salad mixes (raw vegetable salads), peeled baby carrots, broccoli florets, cauliflower florets, cut celery stalks, shredded cabbage, cut melon, sliced pineapple, and sectioned grapefruit.[2] Fresh-cut produce does not require additional preparation, processing, or cooking before consumption, with the possible exception of washing[3] or the addition of salad dressing, seasoning, or other accompaniments. As the fresh-cut produce market continues to evolve, the scope of this guidance may need to be modified to address new or novel types of products.

Fresh-cut Produce and Current Good Manufacturing Practice requirements for foods (CGMPs) (21 CFR Part 110) [4]: FDA's regulations in 21 CFR Part 110 establish CGMPs in manufacturing, packing, or holding human food. However, raw agricultural commodities (RACs), as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (the Act), are not subject to the CGMP requirements by virtue of the exclusion in 21 CFR 110.19. Section 201(r) defines a raw agricultural commodity as any food "in its raw or natural state...." Fresh-cut fruits and vegetables are not RACs because they are no longer "in [their] raw or natural state" and instead have become "processed food" as that term is defined in the Act. Section 201(gg) of the Act defines a "processed food" as "any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydrating, or milling." Under 21 CFR 110.3, the definitions in section 201 of the Act apply to Part 110. Thus, fresh-cut fruits and vegetables are appropriately considered "processed foods" and are subject to the CGMPs in Part 110. The conclusion that fresh-cut produce are not RACs is consistent with the preamble to the proposed revisions to the CGMP regulation (44 FR 33238 at 33239, June 8, 1979), which states, when discussing the exclusion for RACs, that such products may be excluded because "food from those commodities is... brought into compliance with the Act at the later stages of manufacturing, processing, packing, or holding." The CGMPs establish food safety practices applicable to processors who manufacture, process, pack, or hold processed food. FDA believes that the recommendations in this guidance complement the CGMPs by suggesting more specific food safety practices for processors of fresh-cut produce.

Fresh-cut Produce and HACCP Systems: A Hazard Analysis and Critical Control Point (HACCP) system is a prevention-based food safety system designed to prevent, reduce to acceptable levels, or eliminate the microbial, chemical, and physical hazards associated with food production (Ref. 6). One strength of HACCP is its proactive approach to prevent food contamination rather than trying to identify and control contamination after it has occurred.

Although HACCP is not currently required for the processing of fresh-cut produce, the United Fresh Produce Association recommends use of HACCP principles, and according to the association, many segments of the fresh-cut produce industry have adopted HACCP principles.[5]

FDA encourages fresh-cut produce processors to take a proactive role in minimizing microbial food safety hazards potentially associated with fresh-cut produce. We recommend that fresh-cut processors consider a preventive control program to build safety into the processing operations for fresh-cut fruits and vegetables. Awareness of the common risk factors discussed in this guidance and implementation of preventive controls determined by a firm to be appropriate to its individual operations will enhance the safety of fresh-cut fruits and vegetables. FDA also recommends that processors encourage the adoption of safe practices (See Chapter IV) by their partners throughout the supply chain, including produce growers, packers, distributors, transporters, importers, exporters, retailers, food service operators, and consumers, to ensure that the processor's efforts will be enhanced.

This guidance begins with a discussion of primary production and harvesting of fresh produce in Chapter IV and continues with recommendations for fresh-cut processing in four areas-- (1) personnel health and hygiene, (2) training, (3) building and equipment, and (4) sanitation operations. Following this discussion, the guidance covers fresh-cut produce production and processing controls from product specification to storage and transport. The final chapters provide recommendations on recordkeeping and on recalls and tracebacks.

III. Definitions

The following definitions apply to this guidance.

Adequate quality water: The determination of adequate quality water is based on its use, where adequate quality water for one purpose is not necessarily adequate for another purpose. (1) Where the water does not become a component of the fresh-cut produce, adequate quality refers to water that is safe and sanitary, at suitable temperatures, and under pressure as needed for all uses; and (2) where the water is used in a manner such that it may become a component of the fresh-cut produce (e.g., when such water contacts components, fresh-cut produce, or any contact surface), adequate quality water refers to water that complies with applicable Federal, State, and local requirements.

Fresh fruits and vegetables: fresh produce that is likely to be sold to consumers in an unprocessed (i.e., raw) form. Fresh produce may be intact, such as whole strawberries, carrots, radishes, or tomatoes, or cut from roots or stems during harvesting, such as celery, broccoli, lettuce, or cauliflower.

Fresh-cut fruits and vegetables or fresh-cut produce: fresh fruits and vegetables for human consumption that have been minimally processed and altered in form by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing, prior to being packaged for use by the consumer or a retail establishment (e.g., pre-cut, packaged, ready-to-eat salad mixes). Fresh-cut produce does not require additional preparation, processing, or cooking before consumption, with the possible exception of washing or the addition of salad dressing, seasoning or other accompaniments.

Food hazard: a biological, chemical, or physical agent that is reasonably likely to cause human illness or injury in the absence of its control.

Pathogen: a microorganism capable of causing human illness or injury.

Processing water: water that is used for post-harvest handling of produce, such as washing, cooling, waxing, or product transport.

Standard Operating Procedures (SOPs): Procedures established by an operator for the day-to-day activities involved in the production of safe and wholesome food.

Sanitation Standard Operating Procedures (SSOPs): Procedures established by an operator for the day-to-day sanitation activities involved in the production of safe and wholesome food.

IV. Primary Production and Harvesting of Fresh Fruits and Vegetables

In general, anything that comes into contact with fresh produce has the potential to contaminate it. Fresh produce may become contaminated at any point along the farm -to-table continuum. The major source of microbial contamination of fresh produce is indirect or direct contact with animal or human feces. Once fresh produce has been contaminated, removing or killing the microbial pathogens is very difficult. Prevention of microbial contamination at all steps in the farm-to-table continuum is preferable to treatment to eliminate contamination after it has occurred.

On the farm, potential contamination avenues include contact with untreated manure used as a soil amendment, contaminated water, infected workers, or conditions in the field or packing facility such as unclean containers and tools used in harvesting and packing, and the presence of animals. In transport, conditions such as unclean floors and walls of the transport vehicle and unclean containers can contribute to contamination with pathogens. Thus, it is important that fresh-cut produce processors be aware of the conditions under which their fresh produce is grown, harvested, packed, and transported. Furthermore, knowing your suppliers and what they are doing to minimize risk of contamination is prudent.

To reduce potential contamination, the 1998 "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (GAPs Guide) (Ref. 15) provides recommendations for growers, packers, and shippers to use good agricultural and good manufacturing practices in those areas over which they have control to prevent or minimize microbial food safety hazards in fresh produce. Potential sources of contamination identified in the GAPs Guide are biosolids and manure, water, field workers, equipment, and containers.

We recommend the following practices to ensure that incoming fresh produce is safe and suitable for processing into fresh-cut product:

- Becoming aware of practices used by your suppliers (i.e., growers, packers, coolers, transporters, etc.)
- Evaluating the practices of your suppliers by a knowledgeable food safety expert
- Accepting produce from suppliers who use GAPs, GMPs or other appropriate practice from the farm to the processing facility
- Using a mechanism to verify the use of food safety practices by your suppliers (e.g., letter of certification or guarantee from a supplier)

V. Personnel

This section provides recommendations regarding personnel of an establishment that processes fresh-cut produce. The recommendations address two major areas: worker health and hygiene, and training.

A. Worker Health and Hygiene

Workers can carry microbial pathogens on their skin, in their hair, on their hands, and in their digestive systems or respiratory tracts. Unless workers understand and follow basic food protection principles, they may unintentionally contaminate fresh produce and fresh-cut produce, food contact surfaces, water supplies, or other workers, and thereby, create the opportunity to transmit foodborne illness. Basic food protection practices related to worker health and hygiene fall into two categories, disease control and cleanliness.

1. Disease Control

FDA recommends that employees with direct access (such as processing, storage, and transport workers) and indirect access (such as equipment operators, buyers, and pest control operators) to the production areas of fresh-cut fruits and vegetables follow good hygienic practices for maintaining personal health and hygiene in order to protect the product from contamination.

FDA recommends the following practices to prevent food, food contact surfaces, and food packaging materials from becoming contaminated with microbial pathogens from an employee with an infectious illness or wound:

- Establishing a company policy that requires employees to report any active case of illness to supervisors before beginning work
- Training supervisors to know the typical signs and symptoms of infectious disease

  We recommend that firms train employees to report to their supervisor any information about personal health status or activities relating to diseases transmitted through food. Such information would include reporting an active case of illness. FDA recommends that supervisors be trained to recognize the symptoms of active infectious disease; these symptoms are vomiting, nausea, diarrhea, and abdominal cramps. We recommend that employees with these symptoms be excluded from any operations which may be expected to result in contamination of fresh or fresh-cut produce or food contact surfaces, including equipment and utensils, until the medical condition is resolved.
- Covering cuts and wounds with a suitable water proof dressing when workers with such injuries are permitted to continue working.

  We recommend that firms maintain an adequate supply of bandages that provide protection from any wound. A wound containing pus (such as an open and draining boil or other infected wound) that is located on a part of the body that could contact fresh produce or fresh-cut produce, processing equipment, or tools, presents a risk of contaminating fresh-cut produce. When a worker in the processing area needs a bandage, we recommend that the firm consider using a bandage that is detectable by a metal detector if there is a metal detector in the processing line. Using detectable bandages will allow the facility to detect when a bandage has fallen into the processing line so that corrective action can be taken.We also recommend that a worker with a wound that cannot be covered to prevent contact with fresh produce or fresh-cut produce, processing equipment, or tools not work with any aspect of fresh produce or fresh-cut produce, processing equipment or tools until the wound has healed.

2. Cleanliness

FDA recommends that employees use the following food protection practices to prevent fresh or fresh-cut produce or food contact surfaces including equipment or utensils from becoming contaminated as a result of poor employee hygiene or inappropriate employee conduct:

- Maintaining adequate personal cleanliness
- Washing hands frequently and effectively and sanitizing hands if needed

  FDA recommends that employees wash their hands before beginning work and after engaging in any activity that may contaminate their hands. FDA's recommendations regarding when employees should wash their hands are reflected in the following list

  1. Before beginning work, especially if the employee has direct contact with fresh produce
  2. Before putting on a new pair of disposable or non-disposable gloves and after removing the gloves
  3. After touching human body parts or anything other than food or food contact surfaces
  4. After using the toilet; after coughing, sneezing, using a handkerchief or tissue
  5. After using tobacco, eating, or drinking
  6. After engaging in any activity that may contaminate hands, such as handling garbage, cleaning chemicals, or incoming produce before it has been washed
  7. After caring for or touching animals
  8. Before returning to a workstation

- Washing and sanitizing non-disposable gloves before starting work, and as needed
- Changing disposable gloves whenever contamination is a possibility

  Improperly used gloves may become a vehicle for spreading pathogens. The use of gloves does not lessen the need for, or importance of, hand-washing and other proper hygiene practices. We recommend that if gloves are used in a facility, the firm develop guidelines for their safe use, sanitation, and changing.
- Wearing appropriate attire on the job

  FDA recommends that employees wear clean clothes and any additional outer items (e.g., hairnets and beard covers, lab coats, aprons, and appropriate footwear) that will help protect fresh and fresh-cut produce from inadvertent contamination during processing.
- Not engaging in certain activities where food may be exposed or utensils are washed

  FDA recommends that employees in food processing areas not engage in activities that could contaminate food, such as eating, using tobacco, chewing gum, or spitting.

B. Training

Training every employee about the CGMPs and preventive controls will help to eliminate or minimize contamination of fresh-cut produce. We recommend that education and training programs be designed to help employees understand what is expected of them and why what is expected is important. We also recommend that company expectations for proper employee hygiene and food protection techniques be clearly communicated to new employees before starting employment and reaffirmed during periodic training programs. There are many materials available to firms to support employee training. We recommend that firms consider whether the language of the training and training materials is appropriate for the employees. Useful materials and information may be found at the **Fight BAC! (http://www.fightbac.org)**® campaign of the Partnership for Food Safety Education, and Gateway to Government Food Safety Information (**http://www.FoodSafety.gov/) (http://www.foodsafety.gov/)**.

Training employees before they begin work with fresh or fresh-cut produce, at regular intervals, and at a minimum annually provides employees with important information about food safety best practices and company policies. We recommend that firms consider teaching, in the same training session, only a small number of employees at or near their workstation, if the environment permits it, for short periods of time, such as 10-15 minutes per session. The sessions could cover only one topic at a time and could be targeted to specific food safety concerns of that workstation. For example, washing station employees could be trained about appropriate antimicrobial chemical usage, and packaging station employees could be trained about proper handling and cleanliness of boxes and totes. We recommend refresher or follow-up training to reinforce the initial training. Training a few employees at a time can be an effective way to provide refresher training with the least disruption to work.

A firm may wish to post signs and pictorial representations of good practices covered in training as an additional way to reinforce training. We recommend that signs be multilingual and posted in areas close to where the practice is performed. We also recommend that the training provided to employees be documented so there is a record of the training topics covered and which employees completed it.

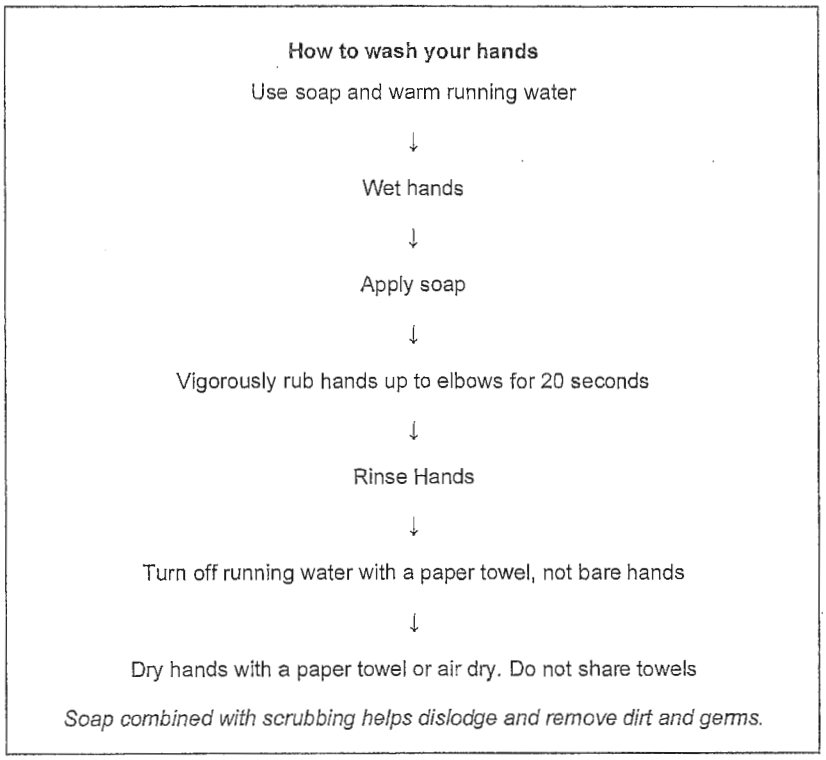
A well-designed training program provides information to help employees apply CGMPs while on the job. We recommend that a fresh-cut produce firm's training program for employees (including temporary, seasonal, and full time employees) include training on the CGMPs for production, maintenance, quality assurance, and quality control with an emphasis on worker health and hygiene; employee roles and responsibilities; and sanitation principles and sanitary practices.

1. Training for Worker Health and Hygiene

We recommend that employees be trained to follow good personal hygiene practices, including the use of proper hand washing techniques, wearing clean clothes and any additional outer coverings (e.g., hairnets and beard covers, disposable gloves, aprons), and appropriate conduct on the job. FDA also recommends that employees be trained on how, when, and to whom to report illness. Hand washing training is particularly important. We recommend that employees be trained about how, when, and why they must properly wash their hands and exposed portions of their arms. We also recommend that employees be taught to wash and sanitize their hands before entering areas where fresh or fresh-cut produce is present.

Figure 1 is an example of an aid that could be used to train employees on the proper technique to use in washing hands:

Figure 1. Example of a training aid on how to wash your hands



2. Training on Employee Roles and Responsibilities

We recommend that employees be trained consistent with the level of complexity of their jobs and that additional training be provided as needed to ensure current knowledge of equipment and process technology.

One goal of a training program is to help workers understand the importance of the tasks for which they are responsible, particularly those tasks that are important to minimizing microbial food safety hazards (such as monitoring the disinfectant level in wash water). We recommend that employees be trained about how to perform these tasks; to be aware of the microbial food safety hazards associated with them; to understand the procedures for monitoring conditions such as the disinfectant level, pH, and the temperature of the wash water, and any associated recordkeeping that the firm chooses to implement; to know the actions that are needed to minimize contamination of the product; and to consult with their supervisors if the established limits (such as the appropriate level of disinfectant in the wash water) are not met.

We recommend that personnel responsible for maintaining equipment that may have an impact on food safety be trained to understand the importance of their role in the production of safe food. Equipment maintenance jobs that may have an impact on food safety include changing water filters, maintaining refrigeration units, treating processing water, and calibrating equipment. We recommend that employees be

trained to identify deficiencies that could affect product safety, to take the appropriate corrective actions (e.g., in-house repairs, contract repairs), and to be able to understand how indirect cross-contamination may occur when proper equipment controls are not maintained.

3. Training on Sanitation Principles and Sanitary Practices

We recommend that employees with cleaning and sanitation duties be trained to understand the principles and methods required for effective cleaning and sanitation, especially as those methods relate to food safety. We recommend that supervisors be trained to identify and promote good sanitary practices.

We also recommend that employees be trained in the proper use of sanitizing agents (sanitizers) and foot foam, foot baths, or spray systems, in proper cleaning and sanitizing steps of the equipment and facility, in proper use of equipment in the production environment, such as hoses and tools, and in the proper use, handling, and storage of chemicals used in sanitation.

Figure 2 is an example of an aid that could be used to train employees on the proper use of sanitizers:

Figure 2. Example of a training aid on proper use of sanitizers

Use sanitizers properly for food safety

Hand sanitizing stations
- After hand washing, sanitize your clean hands with a sanitizer solution
- Allow hands to air dry
- Wash hands and sanitize gloves (disposable or reusable) before wearing
- Re-sanitize your hands after touching non-food contact surfaces

Foot Sanitizer
- When entering any area where fresh produce or fresh-cut produce is present, walk through a foot sanitizer unit

Sanitizer maintenance
- Monitor and change hand and foot sanitizer solutions as needed to maintain effective sanitizer strength, per manufacturer's recommendation

Equipment (whether fixed or free standing), fixtures, floors, walls, and other structures in a processing facility can become a source of microbial contamination if not adequately maintained in sanitary condition. The high humidity and structural niches in a fresh-cut produce processing facility encourage microbial build-up. To prevent fresh-cut produce from becoming contaminated by equipment or other structures in the facility, we recommend that employees be trained on proper cleaning and sanitizing steps within the processing areas.

Figure 3 is an example of an aid that could be used to train employees on the cleaning and maintenance of processing equipment and facilities:

Figure 3. An example of a training aid on cleaning and sanitizing steps within processing areas

Cleaning and sanitizing steps*

1. Remove heavy debris from floors with brooms or shovels and dry clean processing equipment, if needed
2. Pre-rinse the equipment with adequate quality water
3. Clean remaining debris from floor
4. Rinse floor and drains with adequate quality water using a low pressure hose
5. Use dedicated brushes to scrub floor and drains with an effective cleaner, applying adequate quality water as needed
6. Foam and scrub the equipment with an effective cleaner and scrub using dedicated brushes
7. Thoroughly rinse the equipment, floors, and drains with adequate quality water using a low pressure hose
8. Remove excess water from floors

9. Sanitize (according to manufacturer directions) the equipment and floors*

* Work from top down for cleaning and sanitizing activities. Some equipment may need to be disassembled before cleaning and sanitizing followed by reassembly.

In addition to using sanitizers appropriately and cleaning and sanitizing the equipment and facility regularly, proper use of equipment, such as hoses, can also reduce the risk of contamination of fresh and fresh-cut produce. For example, keeping hose nozzles off the floor can help prevent nozzles and employee hands from becoming a source of contamination. We recommend that sections of hose that touch the floor or other unclean surface not make contact with fresh produce, food-contact surfaces, or packaging materials. A retractable hose suspended from the ceiling may help to prevent such contamination. In addition, allowing hose ends to sit in standing water or to be submerged in water tanks could allow back siphonage of water, thereby contaminating the water distribution system.

Further, we recommend that employees be trained to avoid use of high-pressure water hoses to clean floors, walls, and equipment in the processing and packaging areas during production or after production equipment has been cleaned. This practice will help prevent aerosols from contacting processing equipment and food-contact surfaces, product, or packaging materials. Therefore, we recommend that employees be trained on the proper use of cleaning equipment.

VI. Building and Equipment

FDA recommends that the processing facility and its structures (such as walls, ceilings, floors, windows, doors, vents, and drains) be designed to be easy to clean and maintain and to protect the product from microbial, physical, and chemical contamination. For example, designing food contact surfaces to be smooth, nonabsorbent, smoothly bonded, without niches, and sealed would make these surfaces easier to clean and thus, would prevent the harborage of microbial pathogens.

A. Building

Both direct contamination and cross-contamination of produce can be minimized by giving proper attention to physical design, emphasizing proper product flow, using appropriate construction materials, managing facility traffic, and ensuring proper airflow. We recommend that facilities and staging areas be designed to facilitate maintenance and good sanitation practices so that contamination may be controlled throughout receiving, cooling, processing, packing, and storage operations. We also recommend that buildings, fixtures, and equipment be maintained in a condition that will protect fresh-cut produce from potential microbial, chemical, and physical contamination.

1. External/Internal Structures

In general, we recommend limiting access to the facility and to its processing areas, providing adequate space for operations, ensuring adequate drainage of processing and wash water, installing food contact surfaces that are easy to clean and maintain, and designing areas and structures to protect the product and equipment from contamination.

In addition, we recommend the following practices:

- Adequately screening open windows, vents, fans, and similar features to prevent pest (insect, bird, rodent, reptile) entry
- Closing all exterior doors and entrances when not in use and ensuring an adequate seal when exterior doors and entrances are closed
- Properly constructing all walls, ceilings, windows, doors, floors, and overheads (e.g., pipes, air vents, and lights) and maintaining them in good condition (e.g., no cracks, rust, breakage, missing parts, or dips allowing puddles to form) so that they do not harbor pests or pathogens
- Designing properly sloping floors to drains (¼ inch per foot), and sealing and keeping them in good repair so as to provide adequate drainage

- Designing floor drains to prevent the accumulation of water in or around the drains and making drains accessible for cleaning
- Fitting floor drains with seals and grates capable of preventing pest entry
- Using floor flumes with caution due to the potential for water aerosol contamination of the room air and nearby equipment surfaces

  We recommend against the use of a floor flume transfer from the produce cooling and packing operation into or across an area housing fresh-cut produce operations.
- Constructing trench drains for automatic flushing
- Using under-floor drains in fresh-cut produce processing areas
- Designing collection areas for waste stream water to prevent product and equipment contamination
- Designing pipelines to avoid pipe and wall condensation from becoming a source of contamination

  Where overhead condensate cannot be prevented, we recommend that catch pans be utilized, and be cleaned and sanitized on a regular basis.
- Avoiding wood construction materials wherever possible

  If wooden equipment is used (including pallets), we recommend that the equipment be in good condition and well maintained so it is not a source of physical or microbial contamination. Non-wooden construction materials, such as plastic or stainless steel, are preferable for use in processing areas because they reduce the risk of microbial harborage and cross-contamination of final product.
- Using protective guards for light fixtures to prevent broken glass from falling into product

2. Facility Layout

We recommend that a fresh-cut fruit or vegetable processing facility be designed so that incoming raw products never cross paths with or are commingled with finished fresh-cut produce products. Similarly, we recommend maintaining separate raw incoming product, in process, and finished product areas so as to prevent the potential for microbial cross-contamination. Adequate food safety controls, operating practices, and facility design can reduce the potential for contamination by using location and/or flow of humans, product, equipment, and air.

We recommend the following practices that use *location* to reduce the potential for contamination:

- Having rest rooms that open into a location other than a processing area
- Locating the door to the outside in an area other than into a processing area
- Having a microbiology lab that opens into an area other than into a processing area
- Storing in-process and raw produce materials in different rooms
- Establishing dedicated cold rooms for raw product and processed product
- Locating hand washing and sanitizing facilities to facilitate regular and appropriate use by employees
- Locating a disinfectant foot foam, foot bath, or foot spray at all entrances and exits to all production and finished product storage areas.

  We recommend the following practices that use *flow* of personnel, product, equipment, or air to reduce the potential for contamination:
- Having short direct routes for both product and personnel flow
- Designing the plant for one direction of personnel traffic, product, and air flow
- Designing product areas to have traffic patterns that separate raw and finished product using either linear product flow (raw to finished product) or by physical partition

  (Figure 7 in Appendix E is an example of product and personnel flow patterns in a fresh-cut processing plant.)

- Using an air filtration system for central air distribution and airflow that is counter to product flow, so that filtered air moves with a positive pressure from the cleanest areas (e.g., from packaging and finished product storage) toward less clean areas (e.g., the receiving area)

  We also recommend that air intake for the facility be located to minimize contamination of the intake air by:

- Keeping the number of entrances and exits to the processing areas to a minimum
- Restricting the movement of lift trucks, bins, totes, maintenance tools, cleaning implements, clothing, and people from receiving and storage zones to processing and packaging areas

  Color coding bins, totes, clothing, cleaning implements, maintenance tools, and other items (e.g., blue aprons for receiving zones and red aprons for processing and packaging areas) may help achieve separation of traffic and thereby, minimize cross-contamination.

B. Equipment Design, Construction, and Maintenance

We recommend that the processing equipment be designed and constructed to be easy to clean and maintain and to avoid microbial contamination of the fresh-cut product.

1. Equipment Design and Construction

We recommend the following to facilitate cleaning and to help ensure that fresh–cut produce is not contaminated during the processing operation:

- Using smooth, non-absorbent, sealed, and easily cleanable food contact surfaces that are sloped to drain freely and made of durable, non-corrosive, nontoxic materials

  Food contact surfaces include items such as knives, conveyors, belts, chutes, product totes, gloves, tools including shovels and racks, cutting boards, tables, dryers and spinner baskets, and packing scales. We recommend that all food contact surfaces be smoothly bonded (e.g., free of pits, folds, cracks, crevices, open seams, cotter pins, exposed threads, and piano hinges) to avoid harboring pathogens. Where two food contact surfaces meet, we recommend use of a cover over the juncture to prevent food debris from collecting in the crevice and creating an area that is difficult to clean.

- Locating catwalks with open grating so they do *not* pass over areas of exposed fresh or fresh-cut produce or food-contact surfaces
- Designing equipment in the processing area to prevent water collection

  We suggest cautious use of hollow structures, such as catwalk framework, table legs, conveyor rollers, and racks, because they may collect water and debris, and thus, harbor pathogens.

- Elevating food-contact surfaces sufficiently above the floor (with accessibility for cleaning) to prevent contamination from floor splashes
- Installing stationary equipment away from floor drains to allow accessibility to drains for cleaning and to prevent contamination of the equipment

2. Equipment Maintenance

Establishing a preventive maintenance program helps to ensure that all equipment functions as intended. Equipment failure requiring maintenance activities during production may increase the risk of microbial contamination, particularly from *L. monocytogenes* (Ref. 16). Preventive maintenance includes periodic examination and maintenance of equipment such as valves, gaskets, o-rings, pumps, screens, filters, and heat exchanger plates. We recommend that a firm develop appropriate plans of action in case important equipment, such as refrigeration equipment, disinfectant delivery systems, power systems, or alarm systems, malfunctions. We also recommend the following practices:

- Performing maintenance and calibration of equipment by appropriately trained personnel

We recommend that maintenance personnel who work in the processing or packaging areas comply with the hygiene requirements for production employees.

- Installing, calibrating, and maintaining temperature measuring or recording devices as necessary to ensure accuracy
- Frequently sharpening knives, if used, including retractable knives, and disinfecting before use

  We recommend that knives be replaced if damaged or if they cannot otherwise be maintained in a sanitary condition.
- Frequently inspecting cutting blades and belts during processing operations for damage, product residue build up, or cleaning needs

  We recommend that blades be removed and cleaned separately, and remaining equipment parts disassembled (if possible) and cleaned on a regular basis.
- Operating metal detectors in accordance with the manufacturer's instructions and checking for proper functioning at least daily to ensure effective detection of metal and removal of affected product

  We recommend that procedures be in place, such as a the use of metal detectors during packaging operations, to minimize the possibility that metal ends up in finished product packages.
- Calibrating safety control devices that are essential for maintaining the proper level and activity of wash water disinfectant, at a frequency recommended by the manufacturer and documenting this activity on the instrument calibration forms/logs
- Examining air filters for both intake air and compressed air and changing at least as often as the manufacturer specifies, or more frequently if a problem is indicated, such as evidence of filter fouling or perforation

VII. Sanitation Operations

Pathogenic microorganisms may be found on floors, in drains, and on the surfaces of sorting, grading, processing, and packaging equipment. Without appropriate sanitation practices, these surfaces may be a source of microbial contamination.

A. Sanitation Program

We recommend the use of a comprehensive sanitation program developed by a trained employee such as a certified sanitarian to avoid microbial contamination of the product in a fresh-cut processing facility.

We recommend that fresh-cut processors consider using the following practices for their sanitation program:

- Establishing sanitation standard operating procedures (SSOPs), including a cleaning and sanitizing procedure with a regular schedule for all equipment, storage areas, fresh and fresh-cut produce production areas, air systems, and water storage areas

An example of such a schedule is included in Figure 4. When visual inspection or environmental monitoring results for equipment or the facility reveal dirt, food residues, or other debris, we recommend a more frequent cleaning and sanitizing schedule relative to what is shown in Figure 4.

Figure 4. An Example of a Processing Plant Environmental Sanitation Master Schedule[6],[7]

Area	Cleaning/Sanitation Method	Tools	Cleaning Materials	Frequency

Area	Cleaning/Sanitation Method	Tools	Cleaning Materials	Frequency
Area	Cleaning/Sanitation Method	Tools	Cleaning Materials	Frequency
Walls	Foam, brush, rinse	Soft nylon brush and High Pressure Hose (when appropriate)	Chlorine-Quaternary ammonium ("quat")-based cleaner	Once/Month Walls adjacent to processing equipment should be cleaned daily
Ceiling	Foam, brush, rinse	Nylon brush, high pressure machine	Chlorine-quat-based cleaner	Once/Month
Floors	Wash, rinse	Hard bristle broom (not straw), floor scrubbers, low pressure hose	Chlorine-quat-or iodine based cleaner	Daily
Doors	Foam, scrub, rinse	Scouring pad, cloth	Chlorine-quat-based cleaner	Once/Week
Plastic curtains	Foam, rinse	Foam and Rinse	Chlorine-quat-based cleaner	Once/Week
Overhead pipes, electrical conduits, structural beams	Foam, brush	Brush, bucket, high water pressure machine	Chlorine-quat-based cleaner	Once/Month
Hoist, overhead light fixtures	Wipe, clean	Cleaning pad	Water, light detergent	Once/Quarter
Refrigeration coils	Rinse, sanitize	High pressure hose	Water, sanitize with quat	Once/Quarter
Chillers	Scouring	Scouring pad	Acid cleaner	As Needed/Audit
Air distribution filters	Soak	Plastic bins	Chlorine-alkaline detergent	Once/Quarter
Drains, trench	Clean, flood, rinse	Soft Nylon brush, 50 gallon container	Chlorine-alkaline detergent, quat or iodine based sanitizer	Daily
Grids	Brush, rinse	Nylon brush, high water pressure machine	Chlorine-alkaline detergent	Daily
Waste, dumpster areas	Foam, brush, rinse	Nylon brush, high water pressure machine	Heavy duty chlorine-based cleaner	Daily
Employee break rooms/bathrooms	Wash, rinse	Nylon brush, sanitary brushes	Chlorine-based soap or quat	Frequently throughout the day
Maintenance areas	Scrub, rinse	Nylon brush	Degreasing agent	Once/Month

- Including as part of the sanitation schedule the name of the employee (and alternate when primary employee is absent) responsible for the activity, the

equipment to be cleaned and how to disassemble it, the frequency of cleaning, procedures for cleaning (including type and concentration of cleaning compound and sanitizer), time and temperature requirements, cleaning solution flow rate (pressure) if applicable, and the name of an employee responsible for verifying the program effectiveness by inspection

- Cleaning the condenser unit, drip pans, and hoses of refrigerators
- Keeping cold storage as dry as possible
- After cleaning and sanitizing, visually inspecting the area cleaned for product residue and conducting routine microbiological tests (conventional or rapid microbiological methods, such as total count or bioluminescence) to verify effectiveness of the cleaning and sanitizing program
- When reassembling sanitized equipment, placing the equipment parts on a sanitary mat and not on the floor
- Cleaning and sanitizing all processing equipment, facility utilities (e.g., air system, water system), and food-contact surfaces after maintenance work and prior to use in production
- Cleaning and sanitizing processing equipment and food-contact surfaces between the processing of different commodities, if appropriate based on risk
- Avoiding cleaning and sanitizing equipment during processing operations to prevent contamination
- Minimizing splashing during the cleaning of floor drains by using an appropriate brush, such as a ¼ inch smaller brush than the diameter of the drain opening, or a splash guard

  For cleaning drains, we recommend using dedicated utensils (color coded and used for cleaning drains only) to minimize the potential for contamination. We also recommend that floor drains not be cleaned during processing operations and that the person who cleaned drains not clean fresh-cut produce food contact surfaces without changing outer garments, and washing and sanitizing his or her hands.
- Regularly inspecting tools for cutting, slicing, and shredding for damage that could impair cleaning and sanitizing them

  We recommend replacing a tool if it cannot be fixed so that it can be adequately cleaned.

1. Cleaning and Sanitizing Chemicals

Cleaning and sanitizing chemicals may be toxic, and should be stored in dry, secure, and ventilated areas away from facility traffic and processing operations. They should be handled by employees trained in the use of such chemicals.

We recommend the following practices in using cleaning and sanitizing chemicals:

- Using adequate quality water for cleaning and sanitizing at temperatures appropriate for the chemicals used
- Using toxic chemicals for cleaning operations in accordance with the manufacturer's instructions and in accordance with relevant Federal, State, and local government regulations
- Clearly labeling toxic chemicals
- Storing toxic chemicals and pesticides in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials and in accordance with relevant Federal, State, and local government regulations
- Monitoring the effectiveness of cleaning and sanitizing chemicals by visual inspection and environmental testing (especially grooves and niches) for microbial growth

2. Pest Control

We recommend a pest control program be implemented throughout the entire processing facility to eliminate pests (such as rodents, birds, reptiles, and insects) that may harbor or be a vector for a variety of pathogens. As part of the plant's pest

control program, consider frequent monitoring of affected and treated areas to assess accurately the effectiveness of the program. Some helpful physical and chemical controls are recommended below:

- Using window screens, screen doors, and weather stripping for all doors, and air fans at all doorways
- Keeping all exterior doors closed when not in use
- Removing waste products to, and storing waste products in, a location outside the facility
- Removing old, unused equipment from the facility
- Maintaining the exterior grounds surrounding the facility in a manner that will control pest harborage
- Properly storing ingredients, finished product, and food packaging
- Cleaning up spills and produce debris in a timely manner
- Using pesticides, traps, bait, and chemicals that are acceptable for use in a food processing facility and that will not contaminate foods, food ingredients, or food packaging

  Chemical controls should be applied by a licensed pest control operator or according to local regulations.
- Maintaining a map to identify by numbered locations all rodent traps and bait boxes used both inside and outside the processing facility

B. Sanitary Facilities and Controls

1. Employee Changing Facilities and Toilets

We recommend that changing facilities and restrooms be adequate and located in proximity to processing areas, but not so close that they could be a source of contamination. We recommend that restrooms not open directly into processing areas and doors be equipped with self-closing mechanisms or have a maze-type entrance/exit.

2. Hand Washing Facilities

FDA recommends the following practices for employee hand washing facilities:

- Providing a sink, hot and cold running water of adequate quality, effective hand cleaning preparations (e.g., liquid soap), sanitary hand drying devices (such as disposable paper towels), and a waste container
- Installing water control devices (such as knee, foot, or elbow faucet controls) that will protect against contamination of clean hands
- Posting signs that show proper hand washing procedures

We recommend that these signs be posted near the facility entrance, in restrooms, near all hand washing stations, and wherever employees may handle produce, food packaging materials, or food-contact surfaces. We further recommend that these signs be multilingual where some of the workers in the facility are not native English speakers or pictorial where literacy is a concern.

3. Air Quality

Air inside a processing plant can be a vehicle for contamination of food by mold, yeast, dust, or pathogens if not properly controlled. Where fresh and fresh-cut fruits and vegetables are exposed to open air, we recommend that air quality be monitored to ensure that it is of suitable quality.

We also recommend that fresh-cut processors consider the following to maintain appropriate air quality:

- Using positive, negative, and ambient air pressure differentials to direct potential airborne contaminants away from microbially sensitive areas. For example, negative air pressures in raw product areas, microbiology laboratories, and rest

rooms may help to keep air from those areas from flowing into the processing areas. Similarly, positive air pressure can be maintained in areas such as the processing and packaging area.

- If air filtering equipment is used in a fresh-cut processing facility, filters should be performing at manufacturer specified levels of performance
- Filtering compressed air (such as oxygen (O_2), nitrogen (N_2), and carbon dioxide (CO_2) used in modified atmospheric packaging) when such air contacts fresh produce using a 0.3 micron filter (with an efficiency of approximately 75%)

4. Water Supply

Water can be a carrier of microorganisms including pathogens. Adequate quality water is critical in a fresh-cut processing facility because of the absence of a step lethal to pathogens (kill step) in processing the product as well as the presence of factors such as the high degree of product handling, the damage to product during cutting, shredding, etc., and the potential for temperature abuse in processing and storage. We recommend that the water supply in a food processing plant be sufficient for the operations intended and be derived from an adequate source. We recommend that water for operations in the processing facility, such as cleaning and sanitizing the facility and equipment as well as preparing the product for processing, processing the product, and manufacturing ice, be of adequate quality. Where water does not become a component of the fresh-cut produce, we recommend that water be safe and sanitary, at suitable temperatures, and under pressure as needed for all uses. For water that is used in a manner such that the water may become a component of the fresh-cut produce (such as when such water contacts components, fresh-cut produce, or any contact surface), we recommend that water comply with applicable Federal, State, and local requirements.

See Section VIII.C., which provides our recommendations for maintaining water quality used from preparation for processing through processing operations.

We recommend the following practices regarding the water used in a processing facility:

- Complying with applicable Federal, State, and local requirements for water that contacts fresh-cut produce or food-contact surfaces, including water used to make ice

  We recommend that processors protect sources of water and ice from contamination and that ice be manufactured, transported, and stored under sanitary conditions.
- Testing well water, if used, at the site of the well and at the point in the plant most distant from the well on a regular basis to ensure compliance with Federal, State, and local requirements
- Maintaining and inspecting on a routine basis any water charcoal filtering system to prevent it from becoming a source of microbial or physical contamination of water
- Reviewing on a periodic basis water systems to ensure that no cross-connections exist between systems carrying water that is of adequate quality and systems carrying water that is not
- Ensuring that the volume, temperature, and pressure of water is adequate for all operational and clean up demands

5. Environmental Monitoring

FDA recommends an environmental monitoring program designed to detect areas of pathogen harborage and to verify the effectiveness of cleaning and sanitizing programs in preventing cross-contamination. We recommend the following practices:

- Performing environmental sampling on both food contact and non-food contact surfaces (e.g., drains)
- Determining the appropriate target pathogen, test locations, and frequency of sampling

We recommend that the appropriate target pathogen be the most resistant microorganism of public health significance that is likely to occur in fresh-cut produce.

- Focusing environmental monitoring on an indicator organism, such as *Listeria* spp., which indicates microbial contamination but is nonpathogenic and more easily detectable than a target pathogen, such as *L. monocytogenes*
- Establishing a plan for action in the event that a microbiological test indicates the presence of a target pathogen or indicator organism
- Documenting corrective actions and follow-up for all positive microbial test results

VIII. Production and Process Controls

To minimize the potential for the growth of microorganisms and for the contamination of fresh-cut produce, FDA recommends that control measures be in place to prepare, process, package, and store the product.

A. Product Specifications

We recommend that food processors consider developing specifications and controls for all ingredients and components (including raw fruits and vegetables, packaging materials, and gases) that are necessary for production of safe finished product. Specifications provide standards by which a food processor can assess the acceptability of ingredients and components and thus, minimize microbial, chemical, and physical hazards. We recommend, for example, that the fresh-cut processor know as much as possible about the production practices and conditions for the firm's incoming product. The "Guide to Minimize Microbial Food Safety Hazards in Fresh Fruits and Vegetables" (Ref .15) provides useful guidance when reviewing primary production practices.

B. Receipt and Inspection of Ingredients

Opportunities for contamination of fresh produce occur from the field to the processing facility. Loading, transporting, and unloading produce may introduce contaminants. Damaged produce, soil, debris, and pests may all arrive with the produce when it is delivered to the facility. To help ensure the quality of incoming fresh produce, we recommend that the processor carefully inspect the produce upon receipt at the processing facility. We also recommend the following practices:

- Transporting the produce from the field to the processing, packing, or cooling facility as soon as practical after harvest
- Inspecting delivery vehicles carrying fresh produce and other components of the finished product, e.g., cartons, packaging materials, for cleanliness
- Visually inspecting incoming fresh produce for damage, filth, and infestation according to a predetermined sampling plan and rejecting products that do not meet established specifications
- Removing all damaged, moldy, or decomposed product and extraneous matter (such as metal or other foreign material) from in-coming raw ingredients to a designated area
- Retaining information about all incoming ingredients, such as the identity of the grower or supplier, date of harvest, the field, and linking the information on the incoming product with the operation's production records (e.g., when processed, date, shift) for finished product

  This information will be useful in the event a traceback is conducted. See section X in this guide for more information on tracebacks.

C. Specific Processing Steps

1. Preparation for Processing

Appropriate preprocessing of incoming produce can help minimize microbial, chemical, and physical hazards. We recommend that fresh-cut produce processors consider the following activities to help minimize microbial, chemical, and physical hazards in in-coming produce:

- Inspecting fresh produce throughout the processing stream for field contaminants that may not have been noticed during the incoming produce inspection
- Removing from the processing stream damaged or decomposed produce, extraneous matter, and produce that appears to be contaminated by animal feces, fuel, machine grease, or oil
- Removing as much dirt as possible from incoming produce

  We recommend, when appropriate, washing incoming RACs prior to further processing (such as cutting or chopping) to reduce the overall potential for microbial contamination from the surface of intact fruits and vegetables.

2. Processing Water

Water is used extensively in almost all aspects of processing fresh-cut fruits and vegetables, including during cooling, washing, and conveying of produce. Although water may be a useful tool for reducing potential contamination, it may also introduce or spread contaminants. When used for washing, cooling, rinsing, or conveying food, we recommend that water comply with applicable Federal, State, and local requirements.

In a fresh-cut processing operation, water quality changes as the water is used and, thus, maintaining the quality of processing water should be considered. Reusing processing water may present a risk of new or increased number of microbial populations, including human pathogens.

We recommend the following practices:

- Where water is reused in a series of processes, arranging water flow to be counter to the movement of produce through different operations, with the result that as produce is further processed, it is exposed to the cleanest water
- Monitoring and treating processing water for level of disinfectant chemical to ensure the water is maintained in a condition suitable for the application (e.g., washing, cooling, or transporting) and does not become a source of microbial contamination
- Routinely inspecting and maintaining equipment designed to assist in maintaining water quality, such as chlorine injectors, filtration systems, and backflow devices, to ensure efficient operation

  We recommend that ice used on fresh or fresh-cut produce be included in routine water quality testing.

a. Maintaining Water Quality

When used appropriately with adequate quality water, antimicrobial chemicals help minimize the potential for microbial contamination of processing water and subsequent cross contamination of the product. The effectiveness of an antimicrobial agent, as well as the amount that should be used, depends on the treatment conditions, such as water temperature, acidity [pH], water hardness, contact time, amount and rate of product throughput, type of product, water to product ratio, amount of organic material, and the resistance of pathogens to the particular antimicrobial agent. For example, the antimicrobial activity of a chlorine-based disinfectant depends on the amount of hypochlorous acid (also called "free chlorine") present in the water. The amount of hypochlorous acid in the water depends upon the pH of the water, the amount of organic material in the water, and, to some extent, the temperature of the water. If the amount of hypochlorous acid is not maintained when the amount of organic material increases, the antimicrobial agent may lose effectiveness in maintaining water quality. If a fresh-cut processor uses a chlorine containing compound as a disinfectant, we recommend that the processor monitor the processing water for free chlorine or hypochlorous acid concentrations. As another example, the measurement of Oxidation-Reduction Potential (ORP) is used as an indicator of the activity of any antimicrobial agent that is an oxidizer and as a

measure of the agent's effectiveness during processing. Variables that affect antimicrobial activity during processing directly affect the ORP value and may also be used to determine the effectiveness of these oxidizers such as hypoorous acid, hypobromous acid, chlorine dioxide, ozone, and peroxides.

We recommend that fresh-cut processors consider options for maintaining the quality of water most appropriate for their individual operations. Producers may wish to contact a local agricultural extension agent, their chemical supplier, or a food safety consultant for help in deciding what water treatment chemicals to use. In addition, processors may refer to 21 CFR 173.315, "Chemicals used in washing or to assist in the peeling of fruits and vegetables," for additional information about chemicals approved for use in wash water.

We recommend that fresh-cut processors also consider the following regarding water quality maintenance:

- Following the manufacturer's directions for correct mixing of antimicrobial agents to obtain effective concentrations and to minimize safety hazards

  Manufacturers' suggested or allowable levels of antimicrobial chemicals in wash water should not be exceeded.
- Monitoring disinfectant levels frequently in water used for various processing operations to ensure appropriate concentrations are maintained

  Test strips or test kits may be useful for monitoring some disinfectant levels.
- Minimizing the build up of organic material in wash water

  For some operations, filtering recirculating water or using a net to scoop plant material or other debris from tanks may help reduce the build up of organic material.
- Following contact between produce and processing water containing antimicrobial chemicals with a clean water rinse of adequate quality to remove any treatment residues where appropriate and consistent with the manufacturer's directions

b. Washing Fresh Produce

Prior to arriving at the processing facility, RACs may be washed in the field or in a place such as a cooling facility. RACs may also go directly from the field to the processing facility to be washed after receipt. Regardless of where the initial washing of the produce takes place, washing produce can reduce the overall potential for microbial food safety hazards because most microbial contamination is on the surface of the produce. If pathogens are not removed, inactivated, or otherwise controlled at this initial stage, they can potentially spread the contamination to additional produce during processing. Washing RACs before any processing of the produce occurs may reduce potential surface contamination. However, washing, even with disinfectants, can only reduce, not eliminate, pathogens, if present. Washing has little or no effect on pathogens that have been internalized in the produce.

A number of post harvest processes, such as hydrocooling, use of dump tanks, and flume transport utilize a high degree of water-to-produce contact. We recommend that fresh-cut processors use practices to maximize the cleaning potential during these processes and to minimize the potential for cross-contamination.

We recommend the following practices:

- Using a series of washes, if appropriate

  For some operations, a series of washes may be more effective than a single wash. An initial wash treatment may be used to remove the bulk of field soil from produce followed by an additional wash or washes containing an antimicrobial chemical.
- Using appropriate wash methods

  Vigorous washing of produce not easily bruised or injured increases the likelihood of pathogen removal. Different methods may be used to wash different types of produce, including submersion, spray, or both. Regardless of the method used, maintaining the quality of the wash water (see section 2.a. above) is important in order to minimize the potential for contamination.

- Maintaining the efficacy of wash treatments
- Using wash water of an appropriate temperature

  Produce is susceptible to infiltration of wash water if warm produce is placed in water that is cooler than the produce. Such infiltration occurs when the temperature difference creates a pressure differential causing air spaces inside the fruit or vegetable to contract, thereby allowing water to be pulled into the fruit or vegetable. If pathogens are present in the cooling/wash water, they may infiltrate the produce, and subsequent washing will not reduce levels of these pathogens (Refs. 6, 14). Therefore, water used for washing or cooling produce should contain sufficient levels of disinfectant to reduce the potential for pathogens to persist in such water. When it is not practical to reduce the temperature differential between the wash/cooling water and the produce, it is especially important that processors follow practices to minimize pathogens in the water or on the surface of produce. Such practices may include using antimicrobial chemicals in the wash water or using spray type wash treatments instead of submerging produce. Alternatively, produce may be cooled by means other than hydrocooling and then washed with water that is warmer than the produce.

3. Precooling and Cold Storage

Sanitary cold storage of RACs and fresh-cut produce is important to reduce the risk of microbial contamination and potential for subsequent growth. However, most current temperature recommendations for both whole and fresh produce are based on temperatures that maintain quality attributes.[8] Although we recognize that more research needs to be done to identify the types of whole and fresh-cut produce that will support the growth of human pathogens and the temperatures at which this pathogen growth will occur, certain practices can reduce the potential for pathogen growth and contamination during precooling and cold storage.We recommend the following practices to reduce this risk:

- Holding RACs and fresh-cut produce at appropriate cold storage temperatures to reduce the potential for microbial growth
- Preventing condensate and defrost water from evaporator-type cooling systems (e.g., vacuum cooling, cold storage) from dripping onto fresh and fresh-cut produce
- Designing and maintaining forced air cooling to avoid contaminating fresh produce

  In most instances, vacuum cooling or use of fans poses the lowest risk of microbial contamination
- Holding cut melons and any other fresh-cut product determined to need temperature control for safety at ≤ 41° F (≤ 5° C)
- Locating temperature monitoring devices in the warm area of the refrigerator unit (e.g., near the door) and calibrating them on a regular basis
- Inspecting all refrigeration units on a regular basis and keeping them in good operating condition
- Storing similar commodities together (unprocessed product next to unprocessed product and finished product next to finished product) to avoid cross-contamination
- Using an appropriate inventory system to ensure first in first out (FIFO) use and FIFO shipment of raw materials and finished products

4. Washing Fresh-cut Produce: Post-processing Controls

Final washing of fresh produce after cutting, slicing, shredding, and similar fresh-cut processes helps remove some of the cellular fluids that could serve as nutrients for microbial growth. Monitoring the quality of water used in such operations and replacing it at an appropriate frequency as indicated by such monitoring may help prevent the build up of organic material in the water and reduce or prevent cross-contamination of processed produce. We have the following additional recommendations for use after the final wash of processed produce:

- Where appropriate for the product, removing as much excess water as possible from processed produce through draining methods such as spin drying

- Keeping containers used to hold produce (e.g., spin baskets) from direct contact with the floor and away from containers that have had direct contact with the floor (e.g., in cold storage)

D. Packaging

Anything that touches fresh-cut produce has the potential to contaminate it, including the materials used in packaging the finished product.

We recommend the following practices:

- Maintaining an effective system to prevent the use of contaminated, damaged, or defective cartons and totes in order to prevent microbial contamination of the fresh -cut produce during packing operations
- Overseeing incoming materials and gases used in packaging to confirm that they are not damaged or defective and are in appropriate working order
- Rejecting packaging materials that are damaged or contaminated
- Determining the appropriate gas mixtures for products
- Using containers and cartons for their intended purpose only. For example, we recommend against using a carton designated for holding fresh-cut produce to hold tools.
- Storing packaging containers and other packaging materials in a manner so as to protect them from contamination, such as away from pests, dirt, cleaning chemicals, and water condensation from overhead equipment and structures
- Maintaining a program to identify and correct situations where damage to containers may potentially occur
- Labeling all finished fresh-cut produce products with recommended storage instructions (e.g., "Keep Refrigerated") or storage temperature to inform all persons handling the product of the recommended storage conditions

1. Modified Atmosphere Packaging (MAP)

Some packaging controls used for fresh-cut produce affect the environment within the package by reducing the levels of oxygen. Low oxygen levels help maintain the quality of fresh produce and extend shelf-life by slowing respiration and senescence in plant tissues. Oxygen can be reduced passively by using gas permeable films in packaging that result in the natural development of the desired atmosphere; the desired atmosphere is a consequence of the products' respiration as gas diffuses through the film (Ref. 6). Oxygen can also be reduced actively by displacing the mixture of gases in a package with a gas mixture that has a low concentration of oxygen (1-5%). Microorganisms respond differently to the surrounding gases depending on their tolerance. While reduced oxygen and elevated carbon dioxide retard the growth of spoilage microorganisms such as *Pseudomonas spp.*, the same gas conditions may provide growth opportunities for pathogenic microorganisms. At extremely low oxygen levels (< 1%), anaerobic respiration can occur, resulting in tissue destruction that affects product quality and creating the potential for growth of foodborne pathogens such as *Clostridium botulinum* (Ref. 6). It is generally believed, however, that fresh-cut produce will spoil before the toxin becomes a concern (Ref. 6). Non-pathogenic aerobic and facultative microorganisms are present at the time of packaging and persist after packaging.

MAP is only effective in extending shelf-life if used in conjunction with good refrigeration. Elevated temperatures can promote the growth of spoilage organisms and pathogens that may be present. Thus, we recommend that food processors using MAP adhere to strict temperature controls and appropriate shelf-life parameters. Because refrigeration temperatures may not be maintained during distribution of the products or while they are held by retailers or consumers, we also recommend that controls be in place to either prevent increases in temperature, as feasible, or to alert the processor, retailer, or consumer that the product may not be safe to consume. Processors may wish to consider providing product handling guidelines on temperature control and washing to the distributor, retailer, and consumer. Another potential source of contamination of fresh cut produce packed in MAP occurs when the gases, equipment, or packaging materials are not properly maintained. As with

any type of packaging, we recommend that controls be put in place to ensure that the process of packaging the product and the packaging materials themselves do not cause the product to become contaminated.

2. Shelf-life

Fresh-cut fruits and vegetables can cause illness due to contamination with a variety of microorganisms because these products do not undergo any processing to ensure the total elimination of microorganisms that might be present. Some packaging and storage techniques for fresh-cut produce (e.g., MAP, refrigerated storage) may slow the rate of physical deterioration by slowing respiration of the produce. However, if packaging and storage are not properly controlled, pathogens may grow to levels that could render the product unsafe for human consumption. The rate of respiration of fresh produce is inversely related to product shelf-life, which means that a higher respiration rate decreases shelf-life (Ref. 6). Fresh fruits and vegetables that have been cut or otherwise physically altered will have increased respiration, and thus, a shorter shelf-life. To address the risks of increased respiration, we recommend the following practices:

- Communicating (through product labeling) that the consumer should refrigerate the product to prevent product spoilage and the potential for growth of pathogens
- Ensuring that any "use by" date on the product package is validated by studies of the product with respect to microbiological safety

We recommend that records of these data and studies be maintained to document the reliability of the "use by" labeling.

E. Transportation and Storage

We recommend that finished fresh-cut product be stored and transported under conditions that will protect the food against physical, chemical, and microbiological contamination. We recommend, if feasible, that raw whole produce not be stored with finished product and finished product be transported in clean, sanitary vehicles. We also recommend the following practices:

- Keeping finished products refrigerated at temperatures appropriate for the product during storage, transportation, and display for sale to minimize the potential for growth of microbial pathogens
- Equipping refrigerated transportation vehicles and storage rooms with accurate temperature measuring devices, preferably including a temperature recording function

  If a recording temperature device is not used, we recommend that a min/max thermometer, i.e., a thermometer that shows the range of temperatures attained over a set time period, be used.
- Shipping fresh-cut produce products on a FIFO basis to minimize storage time
- Ensuring that the equipment in refrigeration vehicles is designed to circulate cold air uniformly throughout the vehicle while taking the load layout into consideration
- Placing fresh-cut produce products in storage facilities and transportation vehicles in a manner that allows for proper air circulation
- Transporting and storing fresh-cut produce products in vehicles and containers that are dedicated to carrying food products and have been treated by a process that is effective in destroying vegetative cells of microorganisms of public health significance
- Inspecting transportation vehicles and containers for debris, soil, and off-odors prior to loading to increase their suitability for transporting fresh-cut produce
- Loading and unloading fresh-cut produce in a manner that minimizes the potential for damage and for microbial contamination

IX. Documentation and Records

We recommend as a general practice that food processors maintain records sufficient to reflect important product information and practices. Such documentation can be helpful to the processor in several ways. First, such records help ensure consistency of processing operations and end-product quality and safety. They are more reliable than human memory, and they are a useful tool to identify operational areas where inconsistencies occur and further employee training may be needed. Second, maintaining adequate documentation and records of processing operations is important if a traceback investigation of product is ever needed. We recommend that records be retained at the processing plant for at least six months after the date that the products were prepared unless a longer retention time is required under a relevant law or regulation. Records are most useful when they begin by including the date and time, name of person(s) who completed the record, and the activity or production station being recorded.

Records that may be kept for most food processing operations include the following:

- Water quality and supply records
- Water treatment and monitoring records
- Employee training records
- Temperature control records
- Equipment monitoring and maintenance records
- Calibration records
- Sanitation records
- Product processing batch records
- Corrective action records
- Pest control records
- Distribution records
- Inspection records (e.g., incoming product, facility, production area)
- Microbiological contamination records (e.g., food contact surfaces, equipment)

X. Traceback and Recall

Traceback is the process of tracking food items, such as fresh-cut produce, back to their source (growers, packers, processor, field and when harvested). The ability to identify the source of a product can serve as an important complement to food safety programs intended to prevent the occurrence of microbial contamination. Information gained from a traceback investigation may also be useful in limiting the impact of an outbreak of foodborne illness and in identifying and eliminating conditions that may have resulted in the produce becoming contaminated. We recommend that fresh-cut processors establish and maintain written traceback procedures to respond to food safety hazard problems when they arise.

We also recommend that fresh-cut processors establish and maintain a current written contingency plan for use in initiating and carrying out a recall. Having procedures in place will enable the recall of any lot of product that may have been implicated in an outbreak or that tested positive for a pathogen and help provide detailed information to assist the investigation of any foodborne illness associated with the product. Recall procedures usually include the name of the contact persons responsible at all times; the roles and responsibilities for the coordination of a recall; the methods to identify (e.g., use of lot codes), locate, and control recalled products; requirements to investigate other possibly affected products which could subsequently be included in the recall; and procedures for monitoring the effectiveness of the recall.

Because a recall may extend to more than one lot of product, we recommend that processors develop a coding system to help identify incoming product sources, individual production lots and to whom each lot is distributed. Use of package and date codes can help link product packages with production times, equipment, and raw ingredient sources and may facilitate recovery of products during a recall.

In the event of a firm-initiated recall, if a firm believes its product is adulterated or otherwise violates the Act, we request that the firm immediately notify the appropriate FDA district office in the state where the processing facility is located. District office locations are provided in 21 CFR 5.115. (See Appendix A for information to include in the notification.)

Produce growers and packers, fresh-cut produce processors, and shippers are encouraged to work with their partners in growing, transporting, distributing, packing, and processing, and with retail sectors to develop technologies that allow identification of fresh-cut produce from the grower to your operation, to the retailer, and to the consumer.

XI. Additional Information

The following are additional resources for information on how to handle food products safely.

On the web:

1. FDA/Center for Food Safety and Applied Nutrition (/Food/default.htm)
2. Fight BAC! (http://www.fightbac.org)®
3. Gateway to Government Food Safety Information (http://www.foodsafety.gov)
4. Centers for Disease Control and Prevention (http://www.cdc.gov/) (CDC)
5. USDA/Food Safety and Inspection Service (http://www.fsis.usda.gov) (FSIS)
6. NACMCF HACCP guidelines (/Food/GuidanceRegulation/HACCP/ucm2006801.htm)

Other resources:

7. Ednet: a monthly electronic newsletter for food safety educators. To subscribe, send an email message to Listserv@foodsafety.gov (mailto:Listserv@foodsafety.gov). Send the message: Subscribe EDNET-L first name last name.
8. FDA's Outreach and Information Center (/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/ContactCFSAN/default.htm): 1.888.SAFEFOOD
9. Code of Hygienic Practices for Fresh Fruits and Vegetables (CAC/RCP 53-2003)
10. General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003)

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XIII. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 0.067 hour per record for SOP & SSOP maintenance, 40 hours per record for traceback maintenance, 0.067 hour per record for system implementation of a preventive control program comparable to a HACCP system, and 4 hours per record for implementation review of that preventive control program, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. Send comments regarding this

burden estimate or suggestions for reducing this burden to: Office of Food Safety, Division of Plant and Dairy Food Safety (HFS-317), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0609 (expires 10/31/2010).

Appendices

1. Notifying FDA of a Recall
2. Foodborne Pathogens Associated with Fresh Fruits and Vegetables
3. Pathogens Often Transmitted by Food That Has Been Contaminated by Infected Employees
4. Sources of Microbial Contamination
    1. Potential Sources of Microbial Contamination
    2. Examples of Scenarios That May Cause Microbial Contamination of the Product
5. An Example of Product/Personnel Flow Patterns in a Fresh-cut Processing Plant

Appendix A

Notifying FDA of a Recall

In the event of a firm-initiated recall, if a firm believes its product is adulterated or otherwise violates the Act, we request that the firm immediately notify the appropriate FDA district office and that the notification include:

- the identity of the product involved (i.e., an adequate description of the type of food to include brand name and specific variety, date of releasing the food, the lot or code number or other identifier of the implicated product, the quantity and how the food is packaged);
- the reason for the recall and the date and circumstances under which the product deficiency or possible deficiency was discovered;
- an evaluation of the risk associated with the product;
- the total amount of implicated product units processed and the time span of processing;
- the total amount of product in inventory and the total amount of product distributed; the distribution information including the number of direct accounts and, where necessary, the identity of the direct accounts;
- a copy of the firm's recall communication, if any has issued, or the proposed communication if none has issued; the proposed strategy for conducting the recall; and
- the name and telephone number of the firm official who should be contacted concerning the recall

For further FDA guidance on recalls, see 21 CFR sections 7.40-7.59.

Appendix B

Foodborne Pathogens Associated with Fresh Fruits and Vegetables

The U.S. Public Health Service has identified a number of microorganisms associated with foodborne illness that are notable either because of the severity or because of the prevalence of the illness they cause. Foodborne microbial pathogens associated

with the consumption of fresh fruits and vegetables include *Cyclospora cayetanensis*, *Escherichia coli* O157:H7, hepatitis A virus, *Listeria monocytogenes*, Norovirus, *Salmonella* spp., and *Shigella* spp.[9]

- **Cyclospora** infections (cyclosporiasis) are caused by the protozoan *Cyclospora cayetanensis*. The infections are spread by ingestion of food or water contaminated with infected stool. Direct person-to-person transmission is unlikely because excreted oocysts require days to weeks under favorable environmental conditions to become infectious (i.e., sporulate). The natural host for this parasite has not been identified; however, contaminated water used for irrigation and pesticide application and poor worker hygiene have been suggested as the most likely routes of contamination. The infection (cyclosporiasis) is commonly characterized by watery diarrhea, loss of appetite, weight loss, abdominal bloating and cramping, low-grade fever, nausea, vomiting, and fatigue. Relapses and asymptomatic infections can occur. Outbreaks of cyclosporiasis have been linked to fresh raspberries, mesclun lettuce, and basil or basil-containing products. (For more information: *Bad Bug Book*, ***Cyclospora cayetanensis*** **(/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm122216.htm)**)
- ***E. coli* O157:H7** is a bacterium and one of the enterovirulent strains of *Escherichia coli*. Most *E. coli* strains are nonpathogenic, found in the intestines of all animals, including humans, and function by suppressing harmful bacterial growth. However, there are a minority of strains such as serotype O157:H7 that may cause human illness. *E. coli* O157:H7 is a life-threatening bacterium that produces large quantities of potent toxins that can cause severe damage to the lining of the intestines. Human illness associated with *E. coli* O157:H7 infection may include nonbloody diarrhea, hemorrhagic colitis, hemolytic uremic syndrome (HUS), or thrombotic thrombocytopenic purpura (TTP). Hemorrhagic colitis progresses from abdominal cramps to nonbloody diarrhea to bloody diarrhea. HUS largely affects young children and is the leading cause of acute renal failure in children. TTP is a rare syndrome of *E. coli* O157:H7 infection, which largely affects adults and resembles HUS histology. *E. coli* O157:H7 outbreaks have been associated with meat (especially undercooked or raw hamburger), fresh produce, raw milk, unpasteurized apple juice, coleslaw, and contaminated water (For more information: *Bad Bug Book*, ***Escherichia coli*** **(/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm071284.htm)**).
- **Hepatitis A virus** may cause a serious, and sometimes fatal, disease. Hepatitis attributed to hepatitis A virus is characterized by sudden onset of fever, malaise, nausea, anorexia, and abdominal discomfort, followed in several days by jaundice. Hepatitis A virus is excreted in fecal material and is transmitted by the fecal-oral route, which include consumption of contaminated food. The most common food sources of Hepatitis A are shellfish and salads, but it may also be transmitted through drinking water. (For more information: *Bad Bug Book*, **Hepatitis A Virus (/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm071294.htm)**)
- ***Listeria monocytogenes***[10] is a bacterium that causes listeriosis, a serious disease in pregnant women, the elderly, and those with weakened immune systems. *L. monocytogenes* is widespread in the environment (i.e., in soil, water, and decaying vegetation) and has been isolated from domestic animals, humans, raw produce, food processing environments (particularly cool damp areas), and home refrigerators. Outbreaks of listeriosis in the United States have been associated with the consumption of hot dogs, deli or luncheon meats, pate, salami, Mexican-style soft cheeses and butter made with raw milk, and raw vegetables (Ref. 16). (For more information: "**Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods (http://www.foodsafety.gov/~dms/lmr2-toc.html)**")
- **Noroviruses** are a group of related, single-stranded RNA, nonenveloped viruses that cause acute gastroenteritis in humans. Norovirus was recently approved as the official genus name for the group of viruses provisionally described as "Norwalk-like viruses." Norovirus is transmitted by the fecal-oral route most commonly via contaminated water or contaminated foods. Shellfish and salad ingredients are the foods most often implicated in norovirus outbreaks. (For more information: *Bad Bug Book*, **The Norwalk virus family (/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm071344.htm)**

and *CDC*, **Noroviruses (http://www.cdc.gov/ncidod/dvrd/revb/gastro/norovirus.htm)**)

- **Salmonella** is the second most common cause of foodborne illness (salmonellosis) in the United States and is responsible for millions of cases of illness each year. Typical symptoms of salmonellosis are nausea, vomiting, abdominal cramps, fever, mild diarrhea, and headache; these symptoms usually last 6-48 hours. Salmonella outbreaks have been associated with the consumption of raw and undercooked eggs, undercooked poultry and meat, dairy products made with unpasteurized milk, shrimp, fresh produce, and unpasteurized fruit juice. (For more information: *Bad Bug Book*, ***Salmonella* spp. (/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm069966.htm)**)
- ***Shigella* spp.** Humans are a natural reservoir for *Shigella* spp. The primary means of transmission of the shigella organism is by the fecal-oral route. Most cases of infection by shigella (shigellosis) are attributed to the ingestion of food or water contaminated with fecal matter. Contamination has often been associated with poor personal hygiene of food workers. Typical symptoms include abdominal pain, cramps, diarrhea, fever, vomiting, and blood, pus, or mucus in stools. Shigellosis outbreaks have been associated with shredded lettuce, potato salad, green onions, parsley, cheese, seafood, and poultry (Ref. 19). (For more information: *Bad Bug Book*, ***Shigella* spp. (/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm070563.htm)**)

Appendix C

Pathogens Often Transmitted by Food that Has Been Contaminated by Infected Employees*

A wide range of communicable diseases may be transmitted by infected employees to consumers through contaminated food or food utensils. We recommend that fresh-cut produce firms establish an ongoing program to identify employees who present a risk of transmitting foodborne pathogens to fresh produce or to other employees. Below is a list of the most common pathogens that may be transmitted through food and their associated symptoms.

Pathogen	Symptoms
1. Hepatitis A virus	fever, jaundice
2. *Salmonella typhi*	fever
3. *Shigella* species	diarrhea, fever, vomiting
4. Norwalk and Norwalk-like viruses	diarrhea, fever, vomiting
5. *Staphylococcus aureus*	diarrhea, vomiting

Diarrhea, fever, and vomiting are also symptoms of several other pathogens that could be transmitted by food contaminated by infected employees.

Please refer to the **CDC web site (http://www.cdc.gov/foodsafety/disease.htm)** for further information on foodborne diseases, pathogens, and toxins: *.

Appendix D

Figure 5. Potential sources of microbial contamination

- **Ingredients**
  - Raw produce
  - Fresh-cut produce
- **Packaging materials**
  - Containers, films, lids, trays
- **Processing aids**
  - Compressed air
  - Untreated or inadequately treated wash water
  - Ice
  - Reused processing water

- **Facility environment**
  - Ceilings, overhead structures, catwalks
  - Rubber seals around doors (especially coolers)
  - Drains
  - Walls
  - Standing water
  - Wet insulation in walls or around pipes and cooling units
  - Condensate
  - Vacuum cleaner contents
  - Hand washing areas (sinks) and restrooms
- **Food contact surfaces**
  - Fibrous or porous type conveyor belts
  - Filling or packaging equipment
  - Equipment cleaning tools
  - Slicers, dicers, shredders, blenders,
  - Belts, peelers, collators
  - Containers, bins, tubs, or baskets
  - Hands, gloves, and outerwear
  - Ice makers
  - Utensils
- **Nonfood-contact surfaces**
  - In-floor weighing equipment
  - Hollow rollers for conveyors
  - Trash cans and other such ancillary items
  - Visible bearings within equipment
  - Condensate drip pans
  - Maintenance tools (wrenches, screw drivers, etc.)
  - On/off switches
  - Cracked hoses
  - Equipment framework
  - Wet rusting or hollow framework
  - Poorly maintained compressed air filters
  - Motor housing
  - Forklifts, hand trucks, trolleys, racks
  - Vacuum cleaners and floor scrubbers

Figure 6. Examples of Scenarios That May Cause Microbial Contamination of the Product

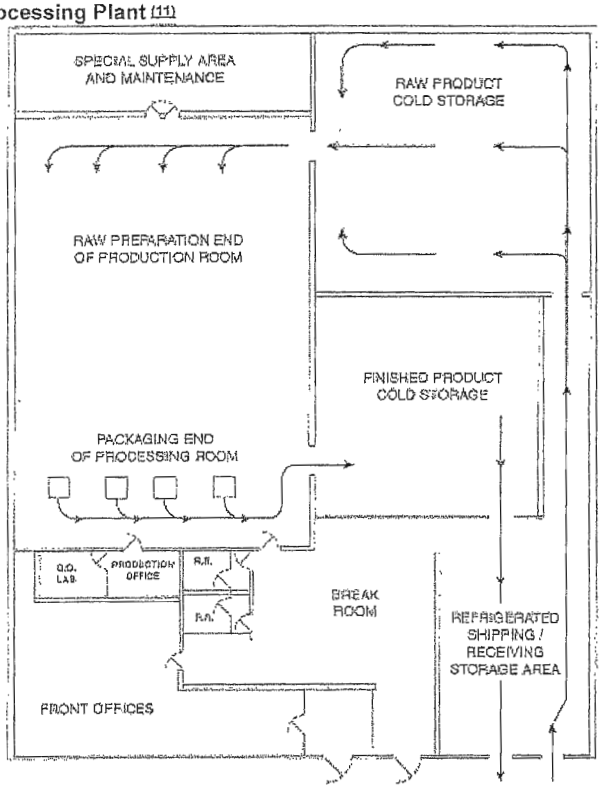
1. A processing line is moved or modified significantly.
2. Used equipment is brought in from storage or another plant and installed into the process flow.
3. An equipment breakdown occurs.
4. Construction or major modifications are made to a fresh-cut produce processing area (e.g., replacing refrigeration units or floors, replacing or building walls, modifications to sewer lines).
5. An employee unfamiliar with the operation and microbial controls has been hired or assigned to work or clean equipment in the processing areas.
6. Personnel who handle fresh produce and fresh-cut produce touch surfaces or equipment that are likely to be contaminated (e.g., floor, trash cans) and do not

change gloves or follow other recommended procedures before handling product.

7. Periods of heavy production make it difficult to change processing water or clean food contact surfaces at the facility as scheduled.
8. A drain backs up.
9. Product is caught or hung up on equipment for an extended period and is not removed during equipment clean-up. Microorganisms may grow in stagnant product and can be a major source of contamination during production. FDA recommends that equipment be modified to eliminate areas where product stops moving along or through a processing line and cannot be readily removed during cleaning.
10. There are frequent product changes on a packaging line which necessitate changing packaging film, labels, forming pockets or molds, line speeds, etc.
11. Personnel are used interchangeably for handling unprocessed produce and finished fresh-cut product.
12. There is increased production requiring wet cleaning of down lines in the same room as lines running product.
13. Equipment parts, tubs, screens, etc. are cleaned on the floor.
14. Waste bins in the processing areas are not properly maintained, cleaned, and sanitized. Personnel handling product may come into contact with these items and then contaminate product and/or product contact surfaces.

Appendix E

Figure 7. An Example of Product/Personnel Flow Patterns in a Fresh-cut Processing Plant (11)



Notes:

[1] This guidance has been prepared by the Division of Plant and Dairy Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

[2] Fresh sprouts are raw agricultural commodities and thus, their production is not governed by 21 CFR Part 110. FDA does, however, recommend that sprouting firms employ current good manufacturing practices. Also, FDA has published specific guidance for the production of sprouts. We recommend that producers of sprouts refer to this guidance, "**Reducing Microbial Food Safety Hazards for Sprouted Seeds (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm120244.htm)**" (Ref. 13) and "**Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm120246.htm)**" (Ref. 14).

[3] For information regarding re-washing of fresh-cut produce, California Department of Health Services Food and Drug Branch "Recommendations from Fresh-cut Produce Re-wash Panel, April 4, 2006." (available in **PDF (http://www.dhs.ca.gov/fdb/local/PDF/Fresh%20cut%20Wash%20Panel%20Backgrounder%20web.pdf)**).

[4] A copy of the **CGMPs in 21 CFR Part 110 (/Food/GuidanceRegulation/CGMP/default.htm)** may be accessed on the internet.

[5] United Fresh Produce Association: **http://www.unitedfresh.org/ (http://www.unitedfresh.org/)**.

[6]Used with permission from the United Fresh Produce Association (UFPA), *Food Safety Guidelines for the Fresh-cut Produce Industry*, 4th Edition, 2001.

[7] Also, as noted previously in section V.B.3., we recommend that employees be trained to avoid use of high-pressure water hoses to clean floors, walls, and equipment in the processing and packaging areas during production or after production equipment has been cleaned. This practice will help prevent aerosols from contacting processing equipment and food-contact surfaces, product, or packaging materials.

[8] An exception is Chapter 1 of the **FDA Food Code (2005) (/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm2016793.htm)**, which defines potentially hazardous food (PHF) and identifies specific fresh produce (among other foods) that is considered PHF and therefore requires refrigeration at 41°F. Cut melons are considered a PHF.

[9] More information about these and other microbiological pathogens can be found in **FDA's Bad Bug Book (/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/default.htm)**. See Ref. 17.

[10] For additional information, FDA, the Centers for Disease Control and Prevention, and the U.S. Department of Agriculture (USDA) have developed a ***Listeria* Action Plan (/Food/FoodborneIllnessContaminants/FoodborneIllnessesNeedToKnow/ucm332272.htm)** (Ref. 18) and a *Listeria* risk assessment (Ref. 16).

[11] Used with permission from UFPA, *Food Safety Guidelines for the Fresh-cut Produce Industry*, 4th Edition, 2001.

The above guidance supercedes the previous version issued March 2007.

Federal Register Notice of Availability February 25, 2008

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FED-STD-209E

The U.S. General Services Administration (GSA) released a Notice of Cancellation for FED-STD-209E, Airborne Particulate Cleanliness Classes in Cleanrooms and Clean Zones, on November 29, 2001.

The Federal Standard 209E cancellation is based on the recommendation by IEST Working Group CC100 that FED-STD-209E no longer be maintained. The IEST, assigned by the GSA as the Preparing Activity organization for FED-STD-209E, has recommended that International Standard ISO 14644, Cleanrooms and controlled environments-Part 1: Classification of air cleanliness, and Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1, supersede FED-STD-209E. ISO 14644-1 and 14644-2 are two parts of a multi-part group of ISO Standards developed by ISO Technical Committee 209 (ISO/TC 209). All ISO/TC 209 Standards may be ordered online through IEST. Click here to enter the IEST Publications Store.

NOTICE OF CANCELLATION FED-STD-209 NOTICE 1
November 29, 2001

FEDERAL STANDARD

AIRBORNE PARTICULATE CLEANLINESS CLASSES
IN CLEANROOMS AND CLEAN ZONES

Federal Standard 209E dated September 11, 1992 is hereby canceled and superseded by International Organization for Standardization (ISO) Standards. International Standards for Cleanrooms and associated controlled environments, ISO 14644-1 Part 1: Classification of air cleanliness; and ISO 14644-2 Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1. Application for copies of ISO Standards 14644-1 Part 1, and 14644-2 Part 2; may be addressed to the Institute of Environmental Sciences and Technology (IEST), 940 East Northwest Highway, Mount Prospect, IL 60056-3444. Phone: 847-255-1561, Fax: 847-255-1699, Web site: www.iest.org, E-mail: publicationsales@iest.org.

Preparing Activity: GSA-FSS
FSC 3694

(Please note that the IEST address changed after the issuance of the notice. The new address is Arlington Place One, 2340 South Arlington Heights Road, Arlington Heights, IL 60005.)

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DEPARTMENT DETERMINATION

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NEXSEN PRUET, LLC
COLUMBIA

Taxpayer:

McEntire Produce, Inc.
P.O. Box 5817
Columbia, SC 29250

Periods Involved:

October 1, 2012 through September 30, 2015

Matters in Dispute:

1. Are McEntire Produce, Inc.'s (Taxpayer) purchases of electricity used to refrigerate produce before and after said produce is processed exempt from sales and use tax pursuant to S.C. Code Ann. § 12-36-2120(19) (2014) as electricity used by manufacturers to manufacture tangible personal property for sale?

2. Are the Taxpayer's purchases of certain supplies[1] exempt from use tax pursuant to S.C. Code Ann. § 12-36-2120(17) (Supp. 2016) as machines used in processing tangible personal property for sale or machine parts used in the operation of such machines?

3. Are the Taxpayer's purchases of safety attire[2] exempt from use tax pursuant to S.C. Code Ann. § 12-36-2120(54) (2014) as "clothing and other attire required for working in a Class 100 or better as defined in Federal Standard 209E clean room environment?"

4. Are the Taxpayer's purchases of safety attire exempt from use tax pursuant to § 12-36-2120(17) as pollution control equipment?

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[1]The supplies at issue include the following: chemicals used for cleaning; bar code scanners for raw produce; black ink aerosol cans; some blower fans; some brooms; cut wheels, discs, and tools; drug test kits; economy pallet truck and stacking containers used for maintenance; floor drain covers; floor scale used to verify weight of raw produce; floor treatment chemicals; forklift rentals, some batteries, and parts; generator rentals for fruit ripening purposes; some lamps; some mobile computer stands; some oil lubricant for hand trucks and pallet jacks, pallet flow brakes and pallet jacks used in raw material part of warehouse; some plastic shelves for maintenance parts room; power supply for maintenance tools; refrigerator to store samples for quality assurance purposes; safety attire; some squeegees; storage water tanks; strip curtains; tools used for maintenance; some towels; some tripod dollies used for maintenance; some utility carts for maintenance tools; warehouse racks for storage of raw and processed produce; some warning signs and stickers; and some whiteboards in the production offices.

[2]Safety attire includes the following: aprons, some coveralls; earplugs, eyewear, gloves, hairnets, shoe covers, sleeve covers, etc.

Amount in Dispute:

$ 126,912.90 Tax
$ 12,346.23 Interest[3]
$ 139,259.13 Total Amount in Dispute

Determinations:

1. The Taxpayer's purchases of electricity used to refrigerate produce before and after said produce is processed are not exempt from sales and use tax.

2. The Taxpayer's purchases of certain supplies are not exempt from use tax as machines used in processing tangible personal property for sale or machine parts used in the operation of such machines.

3. The Taxpayer's purchases of safety attire are not exempt from use tax as "clothing and other attire required for working in a Class 100 or better as defined in Federal Standard 209E clean room environment."

4. The Taxpayer's purchases of safety attire are not exempt from use tax as pollution control equipment.

Relevant Facts:

1. The Taxpayer operates a produce processing facility in Columbia, South Carolina. The Taxpayer processes lettuce, onions, cabbage, tomatoes, and other vegetables (hereinafter "produce") for sale. The Taxpayer's produce processing includes washing, cutting, mixing, and packaging the produce at the Taxpayer's facility. The Taxpayer requires its employees to wear safety attire. In addition to processing the produce, the Taxpayer also stores the produce on storage racks in a refrigerated section of the facility prior to processing and after processing.

2. The Taxpayer has an exemption certificate from the South Carolina Department of Revenue (Department) for its purchases of electricity. The Taxpayer provided that exemption certificate to the seller of electricity.

3. On September 22, 2015, the Department initiated a sales and use tax audit of the Taxpayer for tax periods October 1, 2012 through September 30, 2015.

4. During the audit, the Department reviewed the Taxpayer's purchase invoices and after discussing questionable items with the Taxpayer determined that the Taxpayer failed to report use tax on its purchases of numerous supplies and safety attire. The Department also determined that the Taxpayer failed to properly report sales and use tax on its purchases of electricity for the non-processing portions of the Taxpayer's facility, which included administrative offices and cold storage areas. Specifically, the Department's

[3]Interest is calculated through March 8, 2017, and will continue to accrue until this matter is resolved.

auditor determined that 10% of the Taxpayer's electricity purchases were subject to tax. Accordingly, on July 19, 2016, the Department mailed the Taxpayer a Proposed Assessment showing a total tax due in the amount of $126,912.90.

5. On August 1, 2016, the Taxpayer sent the Department its protest letter. The Taxpayer explained that it believes its purchases of safety attire are exempt from use tax based on Federal safety standards. The Taxpayer also explained that it believes the manufacturing process begins when the Taxpayer receives the raw product and ends when the Taxpayer loads the finished product on trucks for shipment. Based on that belief, the Taxpayer argues that its purchases of electricity for all areas of the facility used for cold storage are exempt from sales and use tax and that all supplies used during that time are exempt from sales and use tax.

6. On August 18, 2016, the Department held a conference with the Taxpayer. During the conference, the Taxpayer reiterated the same arguments it made in its protest letter. However, the Taxpayer did agree that some of the disputed supplies were taxable and agreed to pay the $16,753.30 in tax plus interest due on the purchases of such supplies.[4] The Taxpayer also admitted that approximately 2% of its electricity was used in administrative offices. Despite knowing that at least 2% of its electricity was used for non-exempt purposes, the Taxpayer never remitted sales and use tax on those electricity purchases during the audit period. After attempting to resolve the remaining issues, the Taxpayer elected to have its file forwarded to the Office of General Counsel for Litigation.

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[4]The supplies the Taxpayer agrees are taxable include the following: alert orange windsock; aluminum scaffolding for maintenance; bathroom supplies; some blower fans; Bluetooth headsets; some brooms; cable ties; some coveralls; door parts; doors; some drug test kits; emergency battery lighting; employee folders; eyewash stations; some forklift batteries; gate/door openers; some gloves; industrial Ethernet switches; knockout hole punch tools; labels for human resources; some lamps; some mobile computer stands; some oil lubricant for hand trucks and pallet jacks; some plastic shelves used in the maintenance parts room; respirator storage cabinets in the maintenance parts room; security cameras; shelf cabinets in the maintenance room; some squeegees; stacking containers; steel safety rails; storage cabinets; Tig torch body; some towels; some tripod dollies used for maintenance; some utility carts for maintenance tools; vacuum and portable blower; some warning signs and stickers; welding helmets; some whiteboards in the production offices; and yellow warning magnets. As this list demonstrates, the Taxpayer both agrees and disagrees with the Department regarding the taxability of certain items. However, the Taxpayer failed to elaborate on why it believes some squeegees, for example, but not others should be exempt from use tax.

Analysis:

I. The Taxpayer's purchases of electricity used to refrigerate produce before and after said produce is processed are not exempt from use tax.

A sales and use tax is imposed on the "gross proceeds accruing or proceeding from the sale of electricity." See S.C. Code Ann. §§ 12-36-910(B)(2) & 12-36-1310(B)(2) (2014). Thus, in the absence of an exemption, all sales of electricity to the Taxpayer are subject to sales and use tax. Section 12-36-2120(19) provides an exemption for "electricity used by . . . manufacturers . . . to manufacture[5] . . . tangible personal property for sale." Accordingly, the Taxpayer's purchases of electricity used to manufacture/process tangible personal property for sale is exempt. The remainder of the Taxpayer's electricity purchases, however, is subject to sales and use tax. For example, sales of electricity used in administrative offices, parking lots, and warehouses are not exempt from sales and use tax. See S.C. Code Ann. Regs. 117.302.4. Normally the seller is liable for the sales tax. See S.C. Code Ann. § 12-36-910(A). However, S.C. Code Ann. § 12-36-2510(A)((2)(b) shifts the liability for any tax due from the seller to the purchaser when said purchaser holds an exemption certificate. Accordingly, the Taxpayer, as a purchaser of the electricity who holds an exemption certificate, is liable for the sales and use tax due on its purchases of electricity that are not used to manufacture/process tangible personal property. Thus, the question becomes what percentage of the Taxpayer's electricity purchases is not used to manufacture/process tangible personal property for sale.

The Department determined that 10% of the Taxpayer's electricity purchases were for nonexempt purposes such as providing cold storage for produce before and after processing and supplying power to the administrative offices. It is the Department's understanding that the Taxpayer agrees its electricity purchases used in administrative offices is taxable and is only disputing the Department's denial of the exemption for electricity used for cold storage. In determining whether the electricity used for cold storage was exempt, the Department looked at the plain language in the exemption statute as well as the Department's regulation. Section 12-36-2120(19) exempts only the electricity **used to manufacture or process** tangible personal property. In this case, the Taxpayer's processing activities include washing, cutting, mixing, and packaging produce. That means that only the electricity used in the washing, cutting, mixing, and packaging of the produce is exempt. Keeping produce cold before and after processing does not constitute manufacturing or processing. Thus, electricity used to store produce at a specific temperature does not constitute electricity used to manufacture/process produce. Moreover, Regulation 117-302.4 provides that electricity used to "provide lighting **necessary to the operation of the machines**" and "electricity used to control plant atmosphere . . . in the quality control of tangible personal property **being manufactured**" is exempt but electricity used for any other purpose, such as electricity used in storage warehouses, is not exempt. (Emphasis added). Thus, Regulation 117.302.4 makes it clear that electricity used for anything that is not part of the manufacturing process, such as cold storage, is not exempt from sales and use tax.

[5]For purposes of this exemption, the term "manufacture" includes the activities of processors. See § 12-36-2120(19).

Accordingly, because 10% of the Taxpayer's electricity purchases were for nonexempt purposes, the Taxpayer is liable for the sales and use tax due on 10% of its electricity purchases.[6]

The Taxpayer argues that the analysis applied to the machine exemption – section 12-36-2120(17) – applies to the electricity exemption as well. Section 12-36-2120(17) provides, in part, that "machines **used in manufacturing** [or] processing . . . tangible personal property for sale" are exempt from sales and use tax. (Emphasis added). In construing this statute, courts have determined that the machine exemption applies to more than just machines used in the production line. See Spring Industries, Inc. v. S.C. Dept. of Revenue, Docket No. 99-ALJ-17-0153-CC (S.C. Admin. Law Ct. Nov. 9, 1999); see also Hercules Contractors and Engineers, Inc. v. S.C. Tax Comm'n, 280 S.C. 426, 313 S.E.2d 300 (Ct. App. 1984). The Administrative Law Court (ALC) in Spring Industries determined that because the statute exempts "machines, their parts and attachments when 'used in manufacturing,'" any machinery so used is exempt. Spring Industries, Docket No. 99-ALJ-17-0153-CC. In relying on the Court of Appeals decision in Hercules, the ALC in Spring Industries held the "proper test for the exemption . . . is whether or not the machinery is **'integral and necessary'** to the manufacturing process." Id. (emphasis added). Notably, however, the ALC did not construe the "integral and necessary" test as broadly as the Taxpayer here does. For example, the ALC held that the beam racks that Spring Industries used to store the yarn after it completed a certain level of processing were used for storage purposes only and, thus, were not "essential to nor integral to the production." Accordingly, the ALC Spring Industries held that the beam racks were not exempt from sales and use tax.

Based on the above test for the machine exemption, the Taxpayer argues that its cold storage is integral and necessary to the overall manufacturing process, and therefore, the electricity used for cold storage constitutes electricity used to manufacture tangible personal property. However, the language of the machine exemption and the electricity exemption are not identical. In fact, the electricity exemption is narrower than the machine exemption. While the machine exemption applies to all machines used in manufacturing, which includes all machines that are integral and necessary to the manufacturing process, the electricity exemption applies only to electricity used to manufacture tangible personal property. The General Assembly chose to use the words "used to manufacture" in the electricity exemption as opposed to the words "used in manufacturing." "The language of a tax exemption statute must be given its plain, ordinary meaning and must be strictly construed against the claimed exemption." TNS Mills, Inc., v. S.C. Dept. of Revenue, 331 S.C. 611, 620, 503 S.E.2d 471, 476 (1998) (citing John D. Hollingsworth On Wheels, Inc. v. Greenville County Treasurer, 276 S.C. 314, 278 S.E.2d 340 (1981)). Thus, in giving the language in the electricity exemption its plain, ordinary meaning, the "integral and necessary" test does not apply. Instead, the proper test for the electricity exemption is whether or not the electricity is used to power a machine that makes tangible personal property for sale. Here, the cold storage areas do not make anything. The cold storage areas merely store raw produce prior to processing and finished products prior to shipping. Accordingly, the electricity used to power the cold storage areas is not exempt from sales and use tax.

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[6]10% is the auditor's best estimate. It is entirely possible that more than 10% of the Taxpayer's electricity purchases are for nonexempt purposes. Thus, if it is established that more than 10% of the Taxpayer's electricity purchases are for nonexempt purposes, the Taxpayer will have to report sales and use tax on that nonexempt percentage going forward. The 10% estimate only applies to the audit period.

Even if the "integral and necessary" test did apply to the electricity exemption, the electricity used to power the cold storage areas still would not be exempt. Keeping produce cold before and after it is processed is not "integral and necessary **to the manufacturing process**." Regulating the temperature of the produce in the cold storage areas may be necessary for the storage process. However, just like the beam racks in Spring Industries were not integral and necessary to the yarn manufacturing process because they were solely used for storage, the electricity used to regulate the temperature of a storage area is not integral and necessary to the produce manufacturing process because its sole use is related to storage. Moreover, while keeping the raw produce and the finished produce at a proper temperature may be necessary for health and safety reasons, the Taxpayer has the ability to wash, cut, mix, and package the produce regardless of the temperature. In other words, the temperature of the plant does not affect the Taxpayer's ability to process the produce. Since the temperature of the plant does not affect the Taxpayer's ability to process the produce, regulating the temperature of the plant is not integral and necessary to the processing of the produce. Accordingly, the electricity used to regulate the plant's temperature is not integral and necessary to the manufacturing process and would not be exempt under that test.

Finally, "[t]he burden is on claimants to prove their rights to an exemption by bringing themselves clearly within the conditions imposed by the statute." TNS Mills, 331 S.C. at 618, 154 S.E.2d at 475 (citing York County Fair Assoc. v. South Carolina Tax Comm'n, 249 S.C. 337, 341, 154 S.E.2d 361, 363 (1967)). The electricity exemption narrowly applies to electricity used to manufacture tangible personal property for sale. If the General Assembly intended for the electricity exemption to be as broad as the Taxpayer would like, the General Assembly could have exempted all electricity used by a manufacturer. However, the General Assembly chose to enact a narrow exemption. Accordingly, only the Taxpayer's purchases that fall squarely within the exemption statute are exempt. Because electricity used for cold storage is not used to manufacture or process tangible personal property for sale, such electricity purchases do not fall clearly within the conditions imposed by the electricity exemption statute and, thus, are not exempt from sales and use tax.

II. The Taxpayer's purchases of certain supplies are not exempt from use tax as machines used in processing tangible personal property for sale or machine parts used in the operation of such machines.

S.C. Code Ann. § 12-36-1310(A) (2014) imposes a use tax on "the storage, use, or other consumption in this State of tangible personal property purchased at retail for storage, use, or other consumption in this State . . . ." Thus, in the absence of an exemption, all sales of tangible personal property to the Taxpayer, including the sales of the supplies at issue, are subject to use tax.

The Taxpayer believes that "the manufacturing process begins with the receipt of the raw product and continues until the finished product is loaded on a truck for shipping to a customer . . . ." Based on that belief, it appears the Taxpayer is arguing that the supplies at issue are exempt pursuant to § 12-36-2120(17), despite the fact that S.C. Code Ann. Regs. 117-302.5 (2012) makes it clear that the manufacturing process begins with the first processing machine and ends with the machine that discharges the final product. Section 12-36-2120(17) (hereinafter the "machine exemption") exempts machines used in manufacturing/processing tangible personal

property for sale. Included in the definition of "machines" are "the parts of machines, attachments, and replacements used, or manufactured for use, on or in the operation of the machines and which (a) are necessary to the operation of the machines and are customarily so used . . . ." Id. Courts have determined that the proper test to determine whether a machine or a machine part is exempt from sales and use tax is to determine whether the machine or machine part is integral and necessary to the manufacturing process. See Spring Industries, Docket No. 99-ALJ-17-0153-CC; see also Hercules, 280 S.C. 426, 313 S.E.2d 300. Regulation 117-302.5 incorporates the aforementioned rulings and further elaborates on the machine exemption. The Taxpayer has the burden to prove its right to the machine exemption by bringing itself clearly within the conditions imposed by the machine exemption. See TNS Mills, 331 S.C. at 618, 154 S.E.2d at 475. Thus, the question becomes whether the Taxpayer proved that its purchases of the supplies at issue clearly fall within the conditions imposed by the machine exemption.

Regulation 117-302.5 sets forth several tests to determine whether a machine or machine part is exempt. The first test, which is found in Regulation 117-302.5(B)(1), is based on the Hercules and Spring Industries decisions and sets forth the following test to determine whether a machine or machine part is integral and necessary to the manufacturing process: (1) The machine must be used at a manufacturing facility; (2) The machine must be used in and serve as an essential and indispensable component part of the manufacturing process; (3) The machine must be used on an ongoing and continuous basis during the manufacturing process; and (4) The machine must be substantially used in manufacturing tangible personal property for sale. The Taxpayer failed to establish that any of the supplies at issue satisfy the four part "integral and necessary" test. Accordingly, the Department properly determined that the Taxpayer's purchases of the supplies at issue are taxable.

Regulation 117-302.5(B) also sets forth tests for specific machine parts and attachments, some of which could be pertinent to the supplies at issue if the Taxpayer can satisfy the "integral and necessary" test outlined above. Specifically, Regulation 117-302.5(B)(4) addresses when material handling machinery and/or mechanical conveyances are exempt. Regulation 117-302.5(B)(4) provides, in pertinent part, as follows:

> The machine feeding the first processing machine(s) is exempt. The last machine to come within the exemption is that machine which discharges the finished product from the last machine used in the process. Material handling machinery used for transporting (in process) material from one process stage to another comes within the exemption. **Warehouse machinery used only for warehouse purposes, loading and unloading, storing, transporting raw materials and finished products, etc., is subject to the tax**, unless exempt under the provisions of Code Section 12-36-2120(51). If material handling machinery is customarily used for a dual purpose, that is partly for an exempt purpose and partly for a taxable purpose, and is not otherwise

> exempt under the provisions of Code Section 12-36-2120(51),[7] the machinery may be purchased free of the tax under the machine exemption (Code Section 12-36-2120(17)) provided the exempt use represents a substantial portion of its use.

(Emphasis added). The Taxpayer provided no evidence to establish that the relevant supplies at issue serve any purposes other than warehouse purposes. Accordingly, the Department properly determined that such supplies are taxable.

Regulation 117-302.5(B)(5) addresses when chemicals are exempt. Regulation 117-302.5(B)(5) provides, in relevant part, as follows:

> (a) Chemicals, including greases, oils, lubricants, and coolants, used in an exempt manufacturing machine that are essential to the functioning of the exempt machine during the manufacturing process are integral, necessary, and indispensable to the manufacturing process and are exempt as part of the machine.
>
> * * *
>
> (b) Situations in which the chemicals would not qualify as a part under the machine exemption and would therefore be subject to the sales and use tax, include:
>
> (i) Chemicals used to clean non-exempt machines, such as storage tanks.
> (ii) Chemicals used to clean floors, walls, and other parts of the manufacturing facility.
>
> * * *
>
> (iv) Chemicals, greases, oils (motor oils, gear oils, chain oils), lubricants, and coolants used in an exempt manufacturing machine when such items are not integral and necessary to the manufacturing process, such as those that are not essential in ensuring the functioning of the machine during the manufacturing process.

Again, the Taxpayer failed to establish that the chemicals at issue fit clearly within the conditions imposed above. Rather, the evidence suggests that the chemicals at issue are used to clean floors, walls, and other parts of the manufacturing facility. Accordingly, the Department properly determined that the chemicals at issue are taxable.

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[7]The Taxpayer has not claimed that any of the supplies at issue are exempt under subsection (51), therefore the Department will not further elaborate in this exemption.

Finally Regulation 117-302.5(B)(6), (7), and (10) provide that maintenance machines, machines used for storage, and protective clothing are not exempt under the machine exemption. Accordingly, the Department properly determined that all the supplies that fall under one of those three categories are taxable.

In sum, the Taxpayer failed to bring itself clearly within the conditions imposed by the machine exemption. Accordingly, none of the supplies at issue are exempt from use tax.

III. The Taxpayer's purchases of safety attire are not exempt from use tax as "clothing and other attire required for working in a Class 100 or better as defined in Federal Standard 209E clean room environment."

As discussed under section II above, the Taxpayer's purchases of supplies, including safety attire, are subject to use tax under § 12-36-1310(A) unless exempt. The Taxpayer argues that if its purchases of safety attire are not exempt pursuant to the machine exemption, then most of its safety attire purchases, such as hairnets, gloves, aprons, coveralls, and towels, should be exempt from use tax pursuant to § 12-36-2120(54) as "clothing and other attire required for working in a Class 100 or better as defined in Federal Standard 209E clean room environment."[8] Thus, the question becomes whether the Taxpayer's purchases of safety attire "clearly [falls] within the conditions imposed by the statute." TNS Mills, 331 S.C. at 618, 154 S.E.2d at 475.

Section 12-36-2120(54), the protective clothing exemption, contains two conditions: (1) the Taxpayer must have a Class 100 or better clean room and (2) the safety attire must be required for working in the clean room. The Taxpayer has not established that it meets either of these conditions. First, the Taxpayer notes that the Federal Food and Drug Administration (FDA) recommends that food processors filter their air to 0.3 microns. The Taxpayer claims that it filters its air to 0.1 microns, which is better than what the FDA recommends. However, not only has the Taxpayer not provided documentation to show that it filters its air to 0.1 microns, but such documentation still would not be sufficient for the Taxpayer to satisfy the first condition. In order to qualify as a Class 100 clean room or better, the Taxpayer needs to demonstrate that the amount of particles that are in the air of its plant meet the requirements of being a Class 100 or better clean room. Thus, because the Taxpayer failed to establish that it has a Class 100 or better clean room, the Taxpayer failed to bring itself within the first condition imposed by the protective clothing exemption.

Additionally, the Taxpayer provided nothing to establish that the protective clothing at issue in this case is required for working in a Class 100 or better clean room. In the absence of such evidence, the Taxpayer cannot bring itself within the second condition imposed by the protective clothing exemption. Therefore, the Department properly determined that the Taxpayer's purchases of safety attire are not exempt from use tax pursuant to § 12-36-2120(54).

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[8]In 2001, Federal Standard 209E was cancelled and replaced with International Standards Organization (ISO) 14644-1. Upon information and belief, a Class 100 or better clean room is now classified as a Class 5 or better clean room under ISO 14644-1.

IV. The Taxpayer's purchases of safety attire are not exempt from use tax as pollution control equipment.

As an alternative to the Taxpayer's argument set forth in section III, above, the Taxpayer argues that its purchases of safety attire are exempt pursuant to § 12-36-2120(17) as pollution control equipment. Section 12-36-2120(17) provides an exemption from sales and use tax for machines and its parts and attachments that "are necessary to comply with the order of an agency of the United States or of this State **for the prevention or abatement of pollution of air, water, or noise** that is caused or threatened by any machine used as provided in this section." (Emphasis added). Thus, the question becomes whether the Taxpayer's safety attire is necessary for the prevention or abatement of water, air, or noise pollution.

The Taxpayer provided no evidence that its safety attire prevents or abates any air, water, or noise pollution. In fact, the Taxpayer stated that its safety attire "protect[s] against pollution through contamination of food." Food contamination does not constitute air, water, or noise pollution. Moreover, it is questionable whether food contamination constitutes pollution in general. Accordingly, the Taxpayer's safety attire is not necessary for the prevention or abatement of air, water, or noise pollution. Thus, the Department properly determined that the Taxpayer's purchases of safety attire are not exempt from use tax pursuant to § 12-36-2120(17).

Conclusion:

The Taxpayer operates a food processing plant and purchases various items that are subject to sales and use tax unless otherwise exempt. The Taxpayer argues its purchases of electricity used in its cold storage areas are exempt from sales and use tax pursuant § 12-36-2120(19). However, because the cold storage areas are not used by the Taxpayer to manufacture or process produce, the Department properly determined that such electricity purchases are subject to sales and use tax. The Taxpayer also argues that its purchases of certain supplies, including safety attire, are exempt from use tax pursuant to § 12-36-2120(17). However, the Taxpayer failed to bring itself clearly within the conditions imposed by the statute. Alternatively, the Taxpayer argues that its purchases of safety attire are exempt from use tax pursuant to § 12-36-2120(54) as attire required for working in a Class 100 or better clean room or § 12-36-2120(17) as pollution control equipment. Regarding § 12-36-2120(54), the Taxpayer failed to establish that it has a Class 100 or better clean room and that its safety attire is required for working in such clean room. Regarding § 12-36-2120(17), the Taxpayer failed to establish that its safety attire prevents or abates air, water, or noise pollution and that its safety attire is necessary for such prevention or abatement of pollution. Accordingly, because the Taxpayer failed to bring itself clearly within the conditions imposed by §§ 12-36-2120(17) & (54), the Department properly determined that the Taxpayer's purchases of safety attire are subject to use tax.

February 7, 2017

STATE OF SOUTH CAROLINA

ADMINISTRATIVE LAW COURT

McENTIRE PRODUCE, INC., Petitioner,	)	
vs.	)	Case No.: 17-ALJ-17-0060-CC
SOUTH CAROLINA DEPARTMENT OF REVENUE, Respondent.	)	

DEPOSITION OF DAVID GOMBAS, Ph.D.

DATE: Monday, July 23, 2018

TIME: 10:12 o'clock a.m.

LOCATION: OFFICE OF DAVID GOMBAS
4130 Sunridge Road
Pebble Beach, California 93953

REPORTED BY: THERESA WARD, C.S.R. 9587

A P P E A R A N C E S:

For the Petitioner:

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Respondent's	Description	Page
Exhibit 1	McEntire Produce Site Plan Diagram, Ver. 3, Plant - Downstairs, Bates McEntire 0582	5
Exhibit 2	McEntire Line 4, 5, or 6 Hazard Analysis & Critical Control Point Process Flow Diagram, Bates McEntire 0567	5

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DAVID GOMBAS, Ph.D.

called as a witness, after having been first duly sworn by the Certified Shorthand Reporter to tell the truth, the whole truth, and nothing but the truth, testified as follows:

(Respondent's Exhibits 1 and 2 marked for identification.)

EXAMINATION BY MS. ACQUAVIVA:

Q Okay. Good afternoon, David. We are here in the matter of McEntire Produce, Inc., Petitioner, versus South Carolina Department of Revenue, Respondent, docket number 17-ALJ-17-0060-CC, and my name is Lauren Acquaviva. I'm an attorney for the South Carolina Department of Revenue, and I will be taking a deposition of -- is it doctor? Are you Dr. Gombas?

A Yeah, Dr. Gombas.

Q -- Dr. Gombas, Dr. David Gombas this afternoon. Also present with me on behalf of the Department is Elizabeth Shields, and here on behalf of McEntire Produce is Bernie Maybank and Jim Rourke. Before I get into the basic deposition questions, just because it is a telephone deposition, Dr. Gombas, you are in California while counsel is all here in South Carolina.

Can you just please, for the record, state who is

in the room with you right now?

A The only person in the room with me is the Court Reporter.

Q Okay. And then -- simple enough. We can get started. Will you just state and spell your name for the record?

A David Gombas, G-o-m-b-a-s.

Q Thank you, Dr. Gombas. Have you ever been deposed before?

A Yes.

Q Have you ever been deposed via telephone before?

A No.

Q Okay. Essentially, it will work the same way, just with the understanding you can't have any friends or people in the room kind of helping you along. It's just you have to answer the questions on your own.

A (Witness nodded in the affirmative.)

Q At any time -- and I do not expect this deposition to last very long. I'm hoping it will be under an hour, but if you need a break for any reason or if the Court Reporter needs a break, and same with anybody in the room here in South Carolina, just let me know, and we will go off the record.

Just be aware that during any breaks that we may take, you cannot speak with anybody about the substance of

the deposition. You can talk to people. You just can't talk about this case and the deposition while we're on break. Do you understand?

A Understood.

Q Okay. As I'm sure you're aware from being deposed before, the Court Reporter is going to be reporting everything that we say, and so in addition to the fact that you're on the phone and we can't see you, your responses need to be verbal so the Court Reporter can write them down and so we have something to hear because we won't be able to see a head nod. Do you understand that?

A Understood.

Q Thank you. During the deposition, if you need clarification, if you need the definition of a word or a phrase or you need anything explained, please ask me for that clarification, other than the Court Reporter or counsel for McEntire. Do you understand that?

A Yes.

Q Okay. Since you are allowed to ask me for clarification, if you don't ask for clarification and you answer my question, I am going to assume that you fully understood my question. Is that fair?

A Yes.

Q Okay. Is there anything that would prevent you from testifying accurately and truthfully today?

A Not my knowledge.

Q Okay. How did you prepare for this deposition?

A I looked online at the FDA's Preventive Controls Rule, Part 117, and FDA's Expiring Good Manufacturing Practices Regulation Part 110, and also U.S. FDA's Food Code and the South Carolina Food Code.

Q Okay. Did you speak to anybody in preparation for the deposition?

A Only to Jim Rourke to understand what the deposition was about.

Q Okay. And based on that conversation, what is your understanding of what this deposition is about?

A Based on my conversation, it has to do with a sales tax question regarding protective clothing being purchased by McEntire Produce and the protective clothing being used for the purpose of preventing contamination of produce within the facility.

Q Okay.

A Is that accurate?

Q That, in a nutshell, is a very basic overview of what the deposition will be about. We may explore some things in more detail to see what you may or may not be knowledgeable of. Obviously, if you have no experience with a certain area, we're not going to waste anybody's time asking you questions about it. But generally, yeah,

we're here to talk about one part of the case, which is just protective clothing.

Are you -- how did you become familiar or come to know of McEntire Produce?

MR. MAYBANK: Let me interrupt you. The protective clothing is literally the only issue we've gone over.

MS. ACQUAVIVA: And so that will be the issue that the deposition will be limited to today, is the protective clothing.

BY MS. ACQUAVIVA:

Q Dr. Gombas, how did you become familiar with McEntire Produce?

A McEntire Produce was a member of the trade association I worked for since 2005.

Q Have you done any work with McEntire Produce in the past?

A Only in terms of my work at the trade association.

Q Okay. And what does your work at the trade association entail?

A I was the food safety expert for the fresh produce industry.

Q Okay. And what -- could you describe what your duties were, kind of what being an expert, what services

you provided, things of that nature?

A Primarily guidance to the industry, working with FDA on regulations and guidance, food safety guidance.

Q Okay. For the record, can you tell me a little bit about your educational background?

A I had -- I got my bachelor's in food science at Rutgers University, my master's in food science at Massachusetts Institute of Technology, and my Ph.D. at the University of Massachusetts in food microbiology.

Q Okay. I am going to ask you about your work experience, but first, just in case -- I imagine it may be very extensive. We'll try to limit that based off of your answer to the next couple of my questions.

What did McEntire Produce hire you to do in this case?

A To be an expert witness in regards to food safety related to protective clothing.

Q How much are you being paid to be an expert witness?

A Honestly, I don't know. I did not give them a price. I told them I would be willing to do this pro bono.

Q Okay. And what is your understanding of what you're being asked to do? What is it that McEntire is looking from you, beyond just the general -- being an expert in food safety related to protective clothing, if

anything?

A I'm not sure that there is anything else. It's to provide my experience as an expert -- to serve as an expert witness in this matter.

Q Okay. So then limited to your current or previous job or experience, can you tell me -- essentially go through your resume, but just limit it to your experience related to food safety and protective clothing, specifically.

A Okay. I've been working in the processed and fresh produce industry since -- well, actually, since 1982. My first training course related to protective clothing was in 1989, when I worked for the National Food Processors Association. I continued working in food safety, particularly in good manufacturing practices. From that point on through the current time, I've worked with FDA on their HACCP regulations, H-A-C-C-P. I've worked with FDA on their revision of the good manufacturing practices regulations. I've worked with the processed and fresh produce industries in training on goods manufacturing practices.

Q Okay. Do you have any familiarity with South Carolina law?

A Not specifically. Not specifically, other than what I read this morning, looking at the South Carolina

Food Code.

Q Okay. Have you testified as an expert previously in food safety as it relates to protective clothing?

A No.

Q Have you testified previously as an expert at all?

A Yes.

Q Okay. And what areas -- area or areas, if more than one, have you been qualified as an expert?

A I'm not sure that qualified is -- that I've ever been qualified, per se. But I was asked to be an expert witness in a -- in a suit against Kraft Foods back in 1993.

Q Okay. Did you testify in court?

A No. That was a deposition.

Q I'm sorry. Could you repeat that?

A That was a deposition. That was not in court.

Q Just a deposition. Okay. Have you testified in court at all as an expert?

A Not in the last 40 years.

Q Okay. Let's see. Do you have any background or experience with pollution control?

A I'm not sure I understand the question.

Q In your experience with food safety, have you had the occasion to deal with or encounter controlling pollution in a processing facility?

A Can you define pollution?

Q Pollution would be anything that, for this case specifically, it would be contaminate air, water, or noise pollution is another example, but I would say dealing with something that is a contaminant. You think of smog coming from coal plants as polluting the air, things of that nature.

A Well, under the definition of pollution as a contaminant, yes.

Q Okay. And can you elaborate on that, your experience in that?

A Yes. As a food safety professional and a microbiologist, much of my advice to the industry related to my work with FDA has to do with microbiological contaminants affecting food, both processed food and fresh produce.

Q Okay. In your experience, is the word "pollution" used or is the word "contaminant" used, or both?

A Both can be used.

Q In your experience, how do you define pollution?

A Any contaminant that may be injurious to -- to the intended audience, to the intended consumer.

Q And how, in your experience -- and again, all of my questions are going to go to food safety -- do you

define contaminants?

A Pretty much the same.

Q Okay. So in your -- in your world, so to speak, with food safety, pollution and contaminants are synonymous. Is that accurate?

A Let me modify my definition of both.

Q Okay.

A I said harmful. It's not -- neither one is necessarily harmful. They're perceived as being -- what's the right word? -- objectionable.

Q Okay. But both would be defined -- both the terms "pollution" and "contaminant" would be defined the same way in your field?

A They can be, yes.

Q You said, "They can be," which suggests to me that there are other ways that the terms can be defined. Can you go through some of those other ways?

A In terms of food safety, no, not really. In other aspects, non-food safety, I'm sure there are, but we're limiting this to food safety.

Q Okay. Would you be able to define the term "pollution" generally, outside of food safety?

A Well, I'm just a food safety expert, so my definition of pollution outside of food safety would be pretty much what the general public would say.

Q Okay. So in other words, your expertise is going to be limited to just food safety?

A I would say that's accurate.

Q Okay. Have you read the sales tax exemption that is at issue in this case?

A No, I have not.

Q Okay. Have you had the opportunity to form an expert opinion in this case?

A Yes.

Q Okay. And what is your expert opinion?

A That protective clothing is a necessary protection against contamination or pollution, in the definition that we've been talking about, in any fresh cut or fresh produce handling facility; likewise, any ready-to-eat food processing facility.

Q Okay. Do you know the specific protective clothing that's at issue in this case?

A I do not.

Q Okay. So as far as -- a broad category of protective clothing is what you're speaking about, correct?

A Yes. This would be clothing that would protect the food from contamination from the worker or the worker environment.

Q And when you think -- since you have not been told what the clothing in the case is, when you talk about

protective clothing, what types of items come to mind? What types of things are you talking about or do you deal with often in the food safety world?

A It would be outer clothing, aprons, sleeves, hair nets, caps, gloves and, in some cases, shoes.

Q Okay. And you said that the protective clothing protects food from contamination, correct?

A Yes.

Q Does it do anything else, or is it used for any other purpose, again, in this context?

A The way protective clothing is used in the food industry is, by definition, clothing that is used to protect the food from contamination.

Q Okay.

A That is its primary purpose. If there is a secondary purpose, that would be facility specific.

Q Okay. I think I know the answer to this next question, but I'm going to ask it just so I'm clear, and I'm going off of a little bit of what I learned from the deposition of some McEntire employees.

Can protective clothing ever be used to protect the employee?

A That's a common misperception by the -- well, actually, no. Protective clothing can be used to protect the employee in situations when they are at hazard from the

environment or equipment. For example, stainless steel gloves might protect a worker who is working with cutting machinery.

Q Okay. And one example that I'm going to give you that came up was protective eyewear, when workers would wear them when cutting onions because I know onions make me cry, and so apparently, it does the same for most of the workers. Is that, in your experience, a common use of protective clothing or protective eyewear?

A It can be, yes, but not for food safety.

Q Can protective eyewear be used for food safety, or is that not a typical item?

A I would have to say that is not a typical item.

Q Okay. So it sounds to me, and correct me if I'm wrong, in the food safety context, protective clothing is limited more to the gloves, anything that would cover hair, so hair net, caps, beard net, and then anything that would cover an employee's clothes, such as boots or apron?

A And gloves.

Q And gloves. Is that a general, fair representation of protective clothing as used in the food safety context?

A Generally, yes.

Q Okay.

A Different --

Q I'm trying to understand where your answers are coming from in relation to some of the items at issue.

A Okay.

Q Let me, since you stated that you have not seen the exemptions that we are talking about, let me read it to you, and I'm going to paraphrase parts of it because it's long. So I'm going to read the portion that's relevant to the case. I will read it as slowly as I can, and if you need me to repeat it or any part of it afterwards because you didn't catch it, just let me know. Okay?

A Okay.

Q So essentially, McEntire is asserting that this protective clothing falls under the following exemption, which is machines used in processing that are necessary to comply with the order of an agency of the United States or of this state, which would be South Carolina, for the prevention or abatement of pollution of air, water or noise that is caused or threatened by any machine used as provided in this section.

Did you absorb most of that, if not all of it?

A Yeah. What is the definition of "machine" in this context?

Q There is no black and white definition of "machine" in this context. One of my questions --

A Yeah. In that case, I interpret "machine" to be,

in this context, protective clothing.

Q Okay. And can you elaborate as to how protective clothing could constitute a machine? How would you define "machine" without using the term protective clothing?

A That's outside of my expertise. I'm just -- since you said there is no definition of "machine," I interpreted it as including protective clothing.

Q Okay.

A If one were to substitute "protective clothing" for "machine" in what you just read to me, that's perfectly reasonable.

Q Okay. So I'm going to kind of -- I've broken the exemption down into some what I consider key components, and I'd like to go over those individually with you so I can understand, and I think we did go over this, but I'm going to start with this premise because it will kind of follow through with the rest of the questions on this issue.

What is the pollution at issue in this case?

A In this case, it would be harmful bacteria or allergens.

Q Harmful bacteria or allergens?

A Yes. Actually, harmful microorganisms or allergens.

Q Okay. And for my understanding, why did you make

that correction? What's the difference between bacteria and microorganisms?

A Typically, the bacteria we worry about are listeria, salmonella and pathogenic E-coli, but there can also be viruses which are not bacteria.

Q So does the term microorganism then include bacteria and viruses?

A Yes.

Q It's broader?

A Yes.

Q Okay. I just wanted to understand why we went from bacteria to microorganisms, so that makes sense.

Okay. And again, I understand that you do not know the specifics of the McEntire plant; is that correct?

A I have been in the plant, but it's been a long time.

Q Okay. I mean you understand how the plant works, generally?

A Generally, yes.

Q Okay. And if it's helpful to you, you do have Respondent's Exhibit 1 and 2 there for you to use as necessary. Respondent's Exhibit 1 is a site plan diagram of the McEntire Produce facility, and Respondent's Exhibit 2 is -- and you probably can explain generally what this is better than I can, but from my memory, it's one of the

HACCP flowcharts. They had several of these for different products. This is the one that McEntire chose to use as an example in explaining the process to me, so that is the one that I provided to you.

And when going through Respondent's Exhibit 2, McEntire used cut lettuce as the example finished product that we were -- we were creating.

A Understood.

Q Okay. If you can answer this question, please do so. If not, then just say you don't have sufficient information to answer or whatever other reason you may have to not be able to answer the question.

You said the pollution at issue is harmful microorganisms or allergens. What machine or machines in the plant, processing machines cause or threaten to cause harmful microorganisms or allergens?

A Again, without a definition of machine, it's difficult to answer the question. But the source of the pollution that we're describing here is the incoming produce, the workers and the water that's used in the facility. As such, any piece of equipment that comes in contact with any of those could be a source of contamination of the produce. Likewise, employees' clothing could be a source of contamination of the produce.

Does that answer your question?

Q It gives me a good start to answering my question and some places to follow up, so I think we can get there a little bit more.

You used the word "equipment." And again, if we look at Respondent's Exhibit 2, when you look through the flow chart, you can see some of the equipment that McEntire uses. So they have cutters, which is -- looks like the first little oval, if you go down from the pentagon that says "raw material." Do you see that oval that says "cutting with optional spray"?

A Yes.

Q So they have a cutting machine which would be a piece of equipment. Would you agree that that would be a piece of equipment?

A Yes.

Q They have a flume. They have kind of a shaking device. They described another device, like a large industrial salad spinner for drying, and they have a metal detector. So that's some of the equipment that they use. And then there's all conveyance equipment, whether it's a conveyor belt or a flume, which apparently conveys the water, which also washes the material.

How, if at all, could any of those pieces of equipment cause or create harmful microorganisms or allergens?

A Any food contact equipment can be a source of contamination, so all the ones you described there except for the metal detector, and again, depending on where the metal detector is situated, all of the food contact surfaces that you talked about can be sources of contamination if not properly controlled.

Q Okay. And can you explain how they could be a source of contamination?

A Well, as I described earlier, the type of pollution we're describing here, the microorganisms, the allergens can be coming in on the fresh produce or from the water that is used in the facility. If not properly controlled, those things can contaminate, pollute the equipment, which in turn can pollute a greater range of food.

Q Okay. When you say -- I'm going to use this as an example -- that the harmful microorganisms can come into the plant on incoming produce, how does the microorganism get on the produce to begin with?

A It is a contaminant, pollutant, if you will, that occurs -- generally occurs in the field. It can come from a number of sources. Animals, people or water are the primary vehicles that FDA has identified.

Q Okay. Generally, where do harmful microorganisms come from or how are they created?

A They can come from other humans. They can come from animals or they can be in the soil itself.

Q Okay. Absent contaminated produce, contaminated workers or contaminated water, how could the machines used in McEntire's plant cause microorganisms to grow?

A It is possible for equipment to serve as a harborage for pathogenic bacteria which can then spread through the facility if not controlled.

Q Can you explain a little bit more or elaborate on how a piece of equipment could -- you used the word "harborage" -- could be a harborage for bacteria?

A Uh-huh. The source of bacteria remains the same, from the produce, from the water, from the workers. It comes into the facility. It is spread in the event of inadequate, good manufacturing practices. It comes in contact with a nitch (sic) in the equipment where it has adequate water and nutrients to grow. That's what I refer to as harborage. From the harborage point, it can then be spread through cross contamination.

Q Okay. Again, talking about the microorganisms or allergens and following along with the statutory exemption, what machines prevent or abate the pollution at issue?

A There are a number of tools that a facility has at its disposal to prevent contamination and to prevent harborage in the facility. Some of those are chemicals.

Others are clothing.

Q Okay. Are there any additional clothing from what you mentioned earlier that would be used to prevent or abate the type of pollution we're talking about, the microorganisms?

A There may be, but on a routine, day to day basis, the ones I described earlier are the ones most commonly used to prevent spread of the pollution.

Q Okay. I'd like to go through each of the examples that you gave. So you had gloves, smocks, aprons, shoe coverings, and then I think you said caps or hair -- hair coverings and beard coverings. If you could go through each of those, and if the answer is the same for all of them, for sake of time, that's fine, too, and if you want to group any together, however it's easiest for you to answer, tell me exactly how the specific pieces of protective clothing prevent or abate the microorganisms.

A The answer will be the same for all of them.

Q Okay. That makes it easy.

A The first role of protective clothing is to substitute for the worker's street clothing so that the worker is not bringing the pollution into the facility on their clothes and so not contacting the food with that pollution.

Within the facility, as contamination may occur

from the produce, the water or the equipment, that they aren't -- by using clean clothing and protective clothing, it minimizes the opportunity to spread the contamination on to a broader range of food.

Q Okay. What South Carolina agency order, if any, requires the prevention or abatement of microorganisms?

A Well, certainly, the South Carolina Food Code. I'm not sure what the proper term of that is, but South Carolina has a regulation that pertains to protective -- that includes a provision for the use of protective clothing to prevent contamination of food. That regulation is based on the FDA's food code, 2017.

Q Do you know the regulation number?

A Not offhand.

Q Okay. What federal agency order requires the prevention or abatement of microorganisms?

A The most relevant regulation is FDA's 21 CFR part 117, subpart B, which describes good manufacturing practices for U.S. food facilities or for facilities that process food for consumption in the U.S.

Q And does that regulation specifically state that microorganisms must be prevented or abated?

A I don't know the specific language, but the Food, Drug and Cosmetic Act says specifically that food shall not be adulterated, and the part 117, subpart B provides

requirements to processing facilities on how to comply with that law.

Q All right. In your experience, has the FDA ever given a certified statement saying that protective clothing is necessary to prevent or abate pollution that's caused or threatened by the operation of other machines used in processing of tangible personal property?

A I'm not aware of the FDA putting out a document like you've just described. However, the FDA, on numerous occasions each year cites facilities for inadequate protective clothing to protect food from contamination. Those can be searched by looking for FDA's 483's or warning letters.

Q You said FDA 483's?

A Yes. That's their report of viol- -- violation's too strong a word -- of conditions that need to be corrected in a facility in order to comply with the law.

Q Okay. Do you consider the FDA to be an agency that's primarily charged with the duty of preventing or abating pollution?

A In the context of which we're speaking, yes.

Q Okay. I apologize. I'm just going through my notes to see if there's anything I need to follow up on.

MS. ACQUAVIVA: I don't think I have any additional questions for you. I'll turn it over to

Mr. Maybank for any cross-examination he may have.

MR. MAYBANK: I'm I'll try not to be duplicative. Some of it will obviously be duplicative.

EXAMINATION BY MR. MAYBANK:

Q What are the primary food-bourne contaminants that cause the majority of sickness or death to consumers?

A In the context of fresh produce, there are three bacteria: Listeria, salmonella, pathogenic E-coli, and there are a couple of viruses, norovirus and hepatitis A. There are also parasites, Cyclospora, cryptosporidium being two of the more common contaminants causing food-bourne illness.

Q Okay. And just for 30 seconds or so, can you tell us your experience with E-coli going back from your days in college and master's of Ph.D. (sic)?

A I did extensive food -- extensive research on pathogenic E-coli, listeria and salmonella in terms of ways of preventing their growth and in killing them in food processing.

Q Okay. And just to speed it up a bit, did you study E-coli in your master's or Ph.D. degree?

A No. Those were studied after -- afterwards, during my work experience.

Q Okay. And how about listeria and salmonella? Would that be the same thing?

A Yes.

Q Okay. So in your work experience, just briefly, and you may have already done this, but tell us your work experience study in E-coli, listeria and salmonella.

A I served as lead or primary researcher on a number of papers that discussed mechanisms preventing survival of those organisms in juice and in fresh produce.

Q And how many years have you studied it?

A I think my first paper on salmonella was in the early 1990s.

Q Okay. And did you study it or review it for today?

A I'm sorry. Say that again.

Q And do you still study it and review materials on it through today?

A Yes.

Q Okay. So Black's Law dictionary, which is a lawyer dictionary, it defines pollution as a presence of harmful substances, either physical or gaseous, within a certain area that causes harm to the surroundings, altering the natural environment upon which it has been excreted.

In your opinion, given that definition, is E-coli pollution?

A It is a physical contaminant that would fit within that definition.

Q Okay. So it's a harmful substance?
A Yes.
Q Okay. Does listeria meet that definition of pollution?
A Yes.
Q And how about salmonella?
A Yes.
Q All right. And let me give you a dictionary definition. This is actually Wikipedia. Wikipedia defines pollution as an introduction of contaminants into the natural environment that causes adverse change.
In your opinion, does E-coli meet that definition of pollution?
A Yes.
Q How about listeria?
A Yes.
Q And how about salmonella?
A Yes.
Q And then dictionary.com defines pollution as an introduction of harmful substances or products into the environment.
In your opinion, does E-coli meet that definition of pollution?
A Yes.
Q Does listeria?

A Yes.
Q Does salmonella?
A Yes.
Q Does E-coli, listeria and salmonella, are they sometimes transmitted through air?
A They can be, but rarely.
Q Okay. And how about water?
A Yes.
Q All right. And then we want to focus for a minute or two on just the cutting function. It says -- let me back up a little bit.
Does fresh produce occasionally have E-coli inside it?
A Yes.
Q Okay. Does fresh produce occasionally have listeria inside it?
A Yes.
Q And does fresh produce occasionally have salmonella inside it?
A Yes.
Q And does the cutting of fresh produce in a facility like McEntire, does it -- does it produce, create a release of E-coli, can it?
A It can. If not properly controlled, the organisms you described can be spread to non-contaminated

produce, either directly, through the water or through other food contact surfaces.

Q Okay. And how about listeria? Does cutting of fresh produce that has listeria inside of it, can it also create a release of listeria?

A Yes, and in the same manner.

Q And how about salmonella, the same question in regards to salmonella?

A Yes, in the same manner.

Q All right. And does protective clothing help prevent the spread of E-coli into the cutting room and inside the fresh -- I'm sorry. Does the protective clothing help prevent the spread of E-coli into the cutting room? And I stress into the cutting room as opposed to the cutting process itself.

A Yes. By replacing the street clothing of the workers, it prevents the contamination entering the cutting room from the outside.

Q Okay. And just run quickly -- we don't need a lengthy explanation, but how does -- how would E-coli happen to come into the cutting room, but for the protective clothing?

A E-coli can come into the cutting room from the street clothing of the workers, on their shoes, on their outer clothing, on their hands.

Q And how -- give us some examples. How would it get into their shoes, for example?

A Well, pathogenic E-coli can be present -- it can be present in the parking lot. It can be present on other surfaces that the workers can come in contact with in their normal routine outside, and if they bring that in on their street clothing, it can then contaminate the equipment. It can contaminate the food. It can contaminate the water within the facility. That's why protective clothing, as we've described, is used in the facilities to replace the street clothing that workers have or to cover the street clothing that workers have so any contamination on that clothing will not contaminate surfaces or the food or the water within the facility.

Q Okay. I've heard of E-coli. I've never heard of listeria. How does one come into contact with listeria?

A Listeria is a natural contaminant present in the soil, so -- it grows in the soil, so anyone who is walking through a field or just walking along the street can come in contact with listeria. In most cases, that's not a harmful exposure, but when it comes in contact with the food, the food can then serve as a growth medium for the listeria and, if consumed by people, can cause illness or death.

Q Okay. And same question with regards to

salmonella. How would the workers outside of the plant come into contact with salmonella?

A Salmonella is more of an animal mediated organism. It doesn't grow in the soil, per se. But once the salmonella is present in the soil, on the produce or in the water, any contact with that can then serve as a carriage.

Q Okay. And switching gears to the cutting room itself, does protective clothing help prevent the spreading of E-coli which was already in the cutting room, from getting -- I'll say that again.

Does protective clothing help prevent the spread of E-coli, which is already in the cutting room, for example, by being in a head of lettuce?

A It can. The clothing itself is not antimicrobial, but if the clothing is changed when it becomes dirty, then yes, any contamination that has gotten onto the clothing from the cutting room would then be removed from the cutting room when the worker changes their protective clothing.

Q Okay. Is protective clothing required by federal law in the cutting room?

A Part 117 requires a facility to take whatever measure necessary to prevent contamination of food, and one of the provisions in that regulation specifies the use of

clean clothing in the facility.

Q Okay. A number of states have state regulations regarding protective clothing in restaurants. Would that same regulation apply to protective clothing in a fresh produce facility?

A It has been used in that way. While the food code specifically applies to retail operations, food service, it had -- that same requirement has been applied to ready-to-eat processing facilities.

Q Okay. And you mentioned you have counselled industry on how to comply with FDA rules and regs?

A Yes.

Q And how many years have you done that?

A Since the 1980s, and most recently, last week.

Q Okay. And just real roughly, how many different industries have you counselled? More than a hundred?

A Well, well over a hundred processing facilities and several dozen -- no, over a hundred fresh cut operations, as well. Sorry, fresh produce operations.

Q Okay. And have you written on E-coli, listeria and salmonella?

A Yes.

Q Have you written anything specific on protective clothing?

A I'm thinking, but I don't recall anything

specific on protective clothing.

Q Okay. But you counselled over a hundred businesses on the role of protective clothing and the spread of E-coli?

A Yes, as part of my guidance on the application of good manufacturing practices.

Q Okay. And what would happen if McEntire couldn't afford the sales tax and didn't buy the protective clothing? Would that be against the law?

A It would be a violation of part 117.

Q Okay.

MR. MAYBANK: That's all I have.

MS. ACQUAVIVA: I just have a couple follow up.

FURTHER EXAMINATION BY MS. ACQUAVIVA:

Q You stated, and please correct me if I'm wrong, I believe, that part 117 addresses the use of protective clothing to prevent contamination of food; is that correct?

A Part 117, I think it's subpart 10 addresses protective clothing for the purposes of preventing contamination of food. It's not in those words, but that is the interpretation of it.

Q Do you know what section, whether it's part 117 or otherwise, that talks about preventing the contamination of the air?

A I don't recall.

Q Okay. And do you know if there is a section or regulation that talks about the prevention of contamination of water?

A Yes.

Q And do you know what section that is?

A It would be in subpart B, along the same subpart as the clothing. It's not 10, specifically, but within subpart B of 117, FDA has requirements regarding the handling and treatment of water.

Q And can you elaborate a little bit more on what the -- what those requirements look like?

A They're specifically on the source of the water and on the plumbing used to distribute the water in the facility.

Q Okay. Can you tell me, assuming that there is some type of microbial contamination already in the facility, inside the plant, how would a plant prevent that microorganism from getting into the air, if at all possible?

A Well, the primary approach to controlling harmful microorganisms that are already in the facility are through proper cleaning and sanitation procedures. Those tend to be focused on the equipment and the processing environment. If those procedures are not adequate, there is the opportunity for microorganisms in the facility to become

aerosolized either through poor cleaning procedures or via the air handling system.

Q So just so I understand correctly, then is the only way to prevent that would be proper cleaning of the equipment?

A That is the primary way of doing it, but all the other things we've talked about are likewise necessary to prevent cross contamination. There is no one treatment that is solely responsible. It is the combination of all of the above to prevent harborage of the organism within the facility or cross contamination of the food on organisms that are introduced to the facility either through the food, the workers, water or the environment.

Q Okay. So protective clothing alone could not prevent contaminants from getting into the air, contaminants that are already inside the facility. Is that -- am I understanding that correctly?

A Protective clothing is one tool necessary to prevent contamination coming into the facility or spreading within the facility.

Q What typically is used to prevent microorganisms from getting into the water? And when I say "getting into the water," I mean the waste water, water that would be leaving the plant? How do facilities typically prevent that?

A Preventing harmful microorganisms from leaving the facility?

Q Yeah, from getting -- from basically having a negative impact on the water outside the facility?

A There are ways. The use of chemicals to destroy microorganisms that are in the water, but I'm not aware if or how many operations actually do that because the focus is on making sure that the water is not a source of contamination in the facility or when it's in contact with the food.

Q So are you saying that the focus is on preventing the water inside from being contaminated?

A Yes, on preventing the water from being a source of contamination in the facility when it is in contact with the food.

Q Okay. And again, assuming that there are already -- there is already some type of contamination inside the facility, how does protective clothing prevent that contamination from polluting the air or water or spreading into the air or water? And again, this would be air or water outside the facility. We're looking at an impact on the environment.

A I'm sorry. I'm missing your point. Are you asking how does protective clothing in the facility protect the air or water outside the facility?

Q Would you agree that air or water inside the facility is eventually going to leave the facility?

A Yes.

Q So if air or water inside the facility gets contaminated and it gets out, that would be then polluting the outside air and water. Is that fair to say?

A Honestly, I have no experience in that matter.

Q Okay. Do you know if processing plants like McEntire take any steps or are there any steps they can take to prevent contaminated air or water in the facility from escaping?

A That's never been my focus, so I don't know.

Q Okay. So is it typically then that, with your focus, you're looking at preventing the air and water in the facility from being contaminated?

A Yes.

Q Okay. So then just looking at in the facility, how does, and again, there's already -- we're assuming there is already some type of contamination inside, you know, on a piece of equipment. How does protective clothing prevent the microorganisms from getting into the water or the air?

A As I said earlier, the protective clothing is not antimicrobial, per se, but if the clothing is changed, replaced as needed to prevent -- whenever it becomes

contaminated, that reduces the risk of the contamination spreading to the food, other equipment, the water and, I guess, to the air.

Q Okay. And again, going back to Respondent's Exhibit 2, do you see how they -- McEntire uses water to move the produce and use it as a conveyance? They also use water, chlorinated water to wash the produce?

A Yes.

Q According to McEntire, that water can splash and spill over and it gets on the floor and then goes into the drain.

A Yes.

Q If produce is already contaminated and it's going through this processing system, it's going through the flume and being cut, water splashing all over the place, how does protective clothing prevent the spread of that contamination?

A Again, the primary purpose of protective clothing is to minimize the risk of contamination coming from outside the facility into the facility on the workers.

Secondarily, in the event that there is contamination in the facility, if it gets onto the worker's protective clothing, changing that clothing as necessary whenever it becomes contaminated is an opportunity to reduce the risk of further spread of the contamination,

whether that contamination came from the produce, the water, other equipment, et cetera.

Q Is there anything else that a facility like this would use to prevent further contamination of the water or air?

A Generally, chemicals, cleaning procedures and protective clothing.

Q Okay. And when you say chemicals, can you explain how that would work, how that would prevent a contaminant that's already kind of -- already on the machines, on the conveyors, in the processing section, how that would work, how they would use a chemical to prevent further contamination?

A In the same way you would use chemicals in your kitchen. You have chemicals for cleaning procedures and you have chemicals for sanitizing procedures. Each is intended to remove the pollutants and prevent them from becoming a source of contamination.

Q And when would this cleaning or treating with chemicals take place, typically?

A Generally, a facility has a time between days or other -- at a frequency they define when the equipment is shut down, the processes are shut down, and cleaning and sanitation occurs.

Q So it wouldn't occur anytime during -- while

actual processing is taking place?

A It can, on demand, and depending on the procedures that a facility has. So that's facility specific.

Q Okay.

MS. ACQUAVIVA: And I don't think I have any other questions.

MR. MAYBANK: Just one.

FURTHER EXAMINATION BY MR. MAYBANK:

Q We mentioned several times "best practices." Is there a bible or FDA definition of "best practices," or is that something just people concentrate and do on their own?

A The current good manufacturing practices is codified in part 117, subpart B.

Q Okay.

MR. MAYBANK: That's all I have.

MS. ACQUAVIVA: Okay, Dr. Gombas. I think we are done. Thank you so much for your time this afternoon or this morning, over by you, I guess.

THE WITNESS: My pleasure.

THE COURT REPORTER: I have a question. Who would like a copy of this?

MR. MAYBANK: We'd like one.

MS. ACQUAVIVA: Yeah, I think we both would.

MR. MAYBANK: We'll waive the reading of it.

MS. ACQUAVIVA: That's their decision. If they waive to read and sign the transcript, you can send me the sealed original and then just one copy, and then I think Mr. Maybank would like one copy.

(Whereupon, the proceedings were concluded at 11:25 o'clock a.m.)

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I certify under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Date , 2018

David Gombas, Ph.D.

-o0o-

STATE OF CALIFORNIA)
) ss.
COUNTY OF SANTA CLARA)

I, THERESA WARD, a Certified Shorthand Reporter in and for the State of California, hereby certify that the witness in the foregoing deposition,

DAVID GOMBAS, Ph.D.

was by me duly sworn to tell the truth, the whole truth, and nothing but the truth in the within-entitled cause, and that the foregoing is a full, true, and correct transcript of the proceedings had at the taking of said deposition, reported to the best of my ability, and transcribed under my direction.

Date: August 2, 2018

Theresa Ward, C.S.R. 9587

EXHIBIT C

Stipulations of Fact
McEntire Produce, Inc. v. SC DOR
17-ALJ-17-0060-CC

McEntire Produce v. SCDOR
17-ALJ-17-0060-CC
Respondent's Exhibit 1

File Number	Filing Period	Proposed Notice of Assessment	Tax Paid on Filed Returns	% of Understatement	Interest	Total
040439757	10/31/2012	1,718.16	0.00	171816%	238.90	1,957.06
040439757	11/30/2012	2,335.69	0.00	233569%	318.19	2,653.88
040439757	12/31/2012	1,845.03	0.00	184503%	246.11	2,091.14
040439757	1/31/2013	3,678.58	0.00	367858%	479.83	4,158.41
040439757	2/28/2013	2,327.37	0.00	232737%	297.51	2,624.88
040439757	3/31/2013	2,401.90	0.00	240190%	300.27	2,702.17
040439757	4/30/2013	2,869.79	0.00	286979%	350.62	3,220.41
040439757	5/31/2013	3,628.22	0.00	362822%	629.28	4,257.50
040439757	6/30/2013	7,656.41	0.00	765641%	1,444.28	9,100.69
040439757	7/31/2013	3,658.88	0.00	365888%	678.62	4,337.50
040439757	8/31/2013	3,173.22	0.00	317322%	578.94	3,752.16
040439757	9/30/2013	5,261.65	2.00	262983%	949.04	6,210.69
040439757	10/31/2013	3,331.38	0.00	333138%	636.98	3,968.36
040439757	11/30/2013	2,298.54	2.00	114827%	465.83	2,764.37
040439757	12/31/2013	2,059.98	0.00	205998%	411.31	2,471.29
040439757	1/31/2014	2,660.22	0.00	266022%	522.87	3,183.09
040439757	2/28/2014	2,088.66	0.00	208866%	404.78	2,493.44
040439757	3/31/2014	2,963.93	0.00	296393%	565.60	3,529.53
040439757	4/30/2014	3,522.41	0.00	352241%	661.61	4,184.02
040439757	5/31/2014	3,974.00	0.00	397400%	734.42	4,708.42
040439757	6/30/2014	3,338.31	0.00	333831%	607.42	3,945.73
040439757	7/31/2014	5,794.89	0.00	579489%	1,036.60	6,831.49
040439757	8/31/2014	5,897.30	0.00	589730%	1,037.99	6,935.29
040439757	9/30/2014	4,407.35	0.00	440735%	762.41	5,169.76
040439757	10/31/2014	5,951.11	0.00	595111%	1,011.70	6,962.81
040439757	11/30/2014	5,613.67	0.00	561367%	939.01	6,552.68
040439757	12/31/2014	2,210.93	0.00	221093%	362.93	2,573.86
040439757	1/31/2015	3,547.68	0.00	354768%	571.84	4,119.52
040439757	2/28/2015	2,902.53	0.00	290253%	460.11	3,362.64
040439757	3/31/2015	4,106.21	0.00	410621%	638.81	4,745.02
040439757	4/30/2015	2,741.02	642.00	327%	431.15	3,172.17
040439757	5/31/2015	2,484.38	0.00	248438%	372.45	2,856.83
040439757	6/30/2015	2,332.14	0.00	233214%	342.73	2,674.87
040439757	7/31/2015	6,126.54	0.00	612654%	882.48	7,009.02
040439757	8/31/2015	3,205.05	0.00	320505%	452.53	3,657.58
040439757	9/30/2015	2,799.77	0.00	279977%	387.27	3,187.04
		126,912.90	**646.00**		**21,212.42**	**148,125.32**

CHILLICO
& Associates LLC

January 7, 2019

The Honorable H.W. Funderburk, Jr.
South Carolina Administrative Law Court
Edgar A. Brown Building
1205 Pendleton St., Suite 224
Columbia, SC 29201

RE: McEntire Produce, Inc. v. South Carolina Department of Revenue
Docket No.: 17-ALJ-17-0060-CC

Dear Judge Funderburk,

Enclosed, please find a copy of the Respondent's Proposed Final Order and Decision in the above-referenced matter. Also enclosed is a proof of service. Should you have any questions or need any additional information, please do not hesitate to contact this office.

Sincerely,

Lauren Acquaviva

Lauren Acquaviva

cc: Burnet R. Maybank, Esq.
Jim Rourke, Esq.
Elisabeth W. Shields, Esq. (via e-mail only)
Jason P. Luther, Esq. (via e-mail only)

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

McEntire Produce, Inc.,	)	Docket No. 17-ALJ-17-0060-CC
	)	
Petitioner,	)	
	)	**RESPONDENT'S PROPOSED**
vs.	)	**FINAL ORDER AND DECISION**
	)	
South Carolina Department of Revenue,	)	
	)	
Respondent.	)	
	)	

Appearances:

For the Petitioner: Burnet R. Maybank, III, Esq. and Jim Rourke, Esq.

For the Respondent: Lauren Acquaviva, Esq. and Elisabeth Shields, Esq.

STATEMENT OF THE CASE

This matter comes before the South Carolina Administrative Law Court (the "ALC" or "Court") following McEntire Produce, Inc.'s (the "Petitioner") request for a contested case hearing under S.C. Code Ann. § 12-60-460 (2014). The Petitioner is contesting the South Carolina Department of Revenue's (the "Department" or "Respondent") Determination holding the Petitioner's purchases of certain supplies and protective clothing taxable for tax periods October 1, 2012 through September 30, 2015 (the "Audit Period").

The Department's Determination (the "Determination") concluded that the Petitioner's purchases of certain supplies were not exempt from use tax under S.C. Code Ann. § 12-36-2120(17) (Supp. 2017), and its purchases of protective clothing were not exempt from use tax

under S.C. Code Ann. § 12-36-2120(54) (2014) or § 12-36-2120(17).[1] The Petitioner argues that its purchases of certain supplies are exempt because it claims its processing activities begin when the raw produce is delivered to the plant and ends when the finished product is loaded on its refrigerated trucks for delivery. The Petitioner argues that its purchases of protective clothing are exempt as clothing required for working in a Class 100 or better as defined in Federal Standard 209E clean room environment or, in the alternative, as pollution control machines. The Petitioner also contends that the thirty-six (36) month statute of limitations period applies and, as such, part of the Department's Proposed Assessment falls outside the statute of limitations.

A hearing was held before this Court on November 14 and 15, 2018. At the beginning of the hearing, the parties submitted Stipulations of Fact, which included a list of thirty-five (35) items at issue. After the Petitioner presented its case-in-chief, the Department conceded, based on the testimony presented by the Petitioner, that the Petitioner's purchases of two (2) of the items at issue—refrigerator in quality assurance lab and lamps—are exempt from sales and use tax. Accordingly, the Court must determine whether the Petitioner's purchases of the remaining thirty-three (33) items at issue are exempt from sales and use tax.

ISSUES

The following issues are raised in this proceeding:

1. Are the Petitioner's purchases of certain supplies, listed under "Exhibit A" below, exempt from sales and use tax pursuant to § 12-36-2120(17)?

2. Are the Petitioner's purchases of protective clothing exempt from sales and use tax pursuant to § 12-36-2120(54) or § 12-36-2120(17)?

3. Did the Department timely issue its Proposed Assessment for the Audit Period according to S.C. Code Ann. § 12-54-85(c)(3) (2014)?

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[1]As discussed more fully beginning on page 14, the Determination also concluded the Petitioner's purchases of electricity used to refrigerate produce before and after it's processed is taxable, but that issue was resolved prior to the hearing.

STIPULATIONS OF FACT

At the hearing in this matter and pursuant to Rule 25(C) of the Rules of Procedure for the Administrative Law Court (the "ALC Rules"), the parties entered the following written stipulations of fact into the Record:

1. The Petitioner operates a produce processing facility in Columbia, South Carolina. The Petitioner processes lettuce, onions, cabbage, tomatoes, and other vegetables (hereinafter "produce") for sale. The Petitioner's produce processing includes, but is not limited to, washing, cutting, mixing, and packaging the finished produce at the Petitioner's facility.
2. On September 22, 2015, the Department initiated a sales and use tax audit of the Petitioner for tax periods October 1, 2012 through September 30, 2015 (the "Audit Period").
3. During the audit, the Department reviewed the Petitioner's purchase invoices and after discussing questionable items with the Petitioner determined that the Petitioner failed to report use tax on its purchases of numerous supplies and protective clothing. Accordingly, on July 19, 2016, the Department mailed the Petitioner a Proposed Assessment showing a total tax due in the amount of $126,912.90.[2]
4. The supplies that remain at issue are attached to these Stipulations as Exhibit A.

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[2]Between the issuance of the Department Determination and the hearing in this matter, the Parties were able to agree upon the taxability of some items in dispute. As such, the amount of disputed tax has been reduced from the amount listed in the Department Determination. Additionally, the Petitioner has paid a portion of the tax due on the items it agrees are taxable. A balance in the amount of $18,636.19 in tax remains. The Petitioner agrees that within thirty (30) days of receiving this Court's Final Order it will remit payment in the amount of $18,636.19 plus interest for the items it agrees are taxable. The Department agrees to provide the Petitioner with the updated interest due when the Petitioner informs the Department that it is prepared to submit its payment. The parties agree that if the Petitioner prevails on its statute of limitations argument described in Paragraph 7, that the $18,636.19 amount of tax due will be reduced based on any periods the Court determines are out of statute.

[Exhibit A]

Supplies at Issue

1. Coveralls
2. Eyewear
3. Floor drain covers
4. Warning signs and stickers
5. Gloves
6. Aprons
7. Hairnets
8. Towels
9. Refrigerator in quality assurance lab
10. Blower fan
11. Lamps
12. Warehouse racks
13. Stacking containers
14. Forklift batteries
15. Forklift parts
16. Forklift repair parts
17. Forklift rental
18. Pallet jack
19. Pallet flow brakes
20. Generator rental
21. Bar code scanner
22. Black ink aerosol cans
23. Cleaning machines
24. Plastic shelves for maintenance parts room
25. Maintenance tools
26. Utility cart for maintenance tools
27. Oil lubricant for handtrucks and pallets
28. Cut wheel and disc maintenance tools
29. Brooms
30. Floor treatment chemicals
31. Squeegees
32. Mobile computer stand
33. White boards in production offices
34. Drug test kits
35. Storage water tank

5. On August 1, 2016, the Petitioner timely protested the Proposed Assessment due to the parties' disagreement as to whether the Petitioner's purchase of protective clothing and other supplies (see Exhibit A) are exempt from use tax.

6. While the parties disagree as to the taxability of the items at issue in the Proposed Assessment, the parties agree that the numerical figures and calculations reflected in the Proposed Assessment are accurate. Accordingly, the parties agree that the amount of tax in dispute is $82,305.83 (plus interest).

7. The Petitioner contends that tax periods October 1, 2012 through May 31, 2013 are time-barred.

8. The Petitioner timely requested a contested case hearing.

9. Dr. Gombas is an expert in the use of protective clothing for food safety purposes.

10. The parties stipulate that the deposition transcript of Dr. David Gombas may be used in these proceedings pursuant to Rule 32(a)(3)(B), SCRCP.

11. The parties stipulate to the admissibility of Petitioner's Exhibits 5, 7 – 8, 10 – 11, 14, 16 – 17, and 19 – 25. These exhibits along with Petitioner's complete Exhibit List are attached to the Stipulations as Exhibit B.

12. The parties stipulate to the admissibility of Respondent's Exhibit 1, which is attached to the Stipulations as Exhibit C.

13. The parties stipulate that if the Court determines that some of the items at issue are subject to tax while other items are exempt, this matter should be remanded back to the Department to calculate the tax and interest due on the items deemed taxable by the Court.

FINDINGS OF FACT

Having observed the witnesses and exhibits presented at the hearing and taking into consideration the burden of persuasion and the credibility of the witnesses, I make the following

findings of fact by a preponderance of the evidence:

McEntire's Operations

The Petitioner operates a produce processing plant. As part of its operation, the Petitioner receives raw produce from farms with which the Petitioner contracts. These contracts contain several requirements to prevent the spread of microbiological contaminants such as Salmonella, Listeria, or E-Coli, which may be present in the raw produce at the time the produce is harvested. Once the produce arrives at the Petitioner's plant, which is maintained at a temperature between 33 and 40 degrees[3] in further effort to prevent the spread of microbiological contaminants, the Petitioner's employees inspect the raw produce, discarding any unusable produce, and sort the produce in preparation for processing. The raw produce then sits in one of the Petitioner's storage coolers until the Petitioner is ready to process the produce. Once the Petitioner is ready to turn the raw produce into its finished product, the Petitioner's employees will move the produce from its respective storage cooler to either the tomato re-pack room or the cutting room. After the raw produce is processed, bagged, and boxed, the finished product is palletized then kept in the finished goods storage area. The finished product remains in the finished goods storage area until it is loaded onto the Petitioner's refrigerated trucks and delivered to the customer.

The Tomato Re-Pack Room

The tomato re-pack room is a "low-care"[4] area where whole tomatoes are packaged by

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[3]The following areas of the plant are maintained at a temperature between 33 and 40 degrees: the receiving area, the raw coolers, the tomato coolers, the raw feed area, the Ready-to-Eat area (also called the cutting room or the high-care area), the tomato repack room, the pack-out room, the palletizing room, the finished goods storage rooms, and the shipping area (see Petitioner's Exhibit 8).

[4]Carter McEntire, the Petitioner's President and CEO, testified that the tomato re-pack area is considered a low-care area because the product remains whole; it is not cut and exposed to the environment. Mr. McEntire explained that in a low-care area, employees "are not required to wear

hand according to the customer's specification as to color, size, and weight. Prior to entering the tomato re-pack room, tomatoes that will be re-packed are stored in the tomato coolers while they ripen. Because the Petitioner's customers specify the color tomato they want, the Petitioner has to rent generators on occasion to speed up the tomato ripening to meet the customers' needs. The ripened tomatoes are moved from the tomato coolers into the tomato re-pack room where the tomatoes are sorted and packaged. The packages are then labeled. Finally, the Petitioner's employees move the packaged tomatoes into another cooler to be stored until they are loaded onto the Petitioner's refrigerated trucks for delivery to the customer.

The Cutting Room

The cutting room is a "high-care"[5] area where produce is cut and packaged according to the customer's specifications. When raw produce that will be cut first arrives at the Petitioner's facility, the raw produce is inspected then moved into a storage cooler. When the Petitioner is ready to process the raw produce, the raw produce is moved to the raw feed area where the Petitioner's employees utilize a bin dumping conveyance system to move the produce into the cutting room. Once the produce is in the cutting room, the Petitioner's employees sort, inspect, and trim the produce then place the produce on a conveyor belt. The produce moves down the line to the cutter, which cuts up the produce according to the customer's specifications. Once the produce is cut, it enters the first washing flume, then the dewatering shaker, then the second

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PPG [personal protective gear]. They are required to wear certain items like hairnets." Mr. McEntire did not explain what items are included in "PPG."

[5]Mr. McEntire testified that "[i]n the high-care area . . . [employees] are required to wear all the PPG required by Federal law." In the high-care area, the Petitioner requires its employees to wear hairnets, overshoes, smocks, gloves, and "any other PPG that's required." Mr. McEntire further explained that the purpose of the protective clothing is to "protect the food from the human." Mr. McEntire did not elaborate on the differences between a low-care area and a high-care area.

washing flume, and then the second dewatering shaker. Next, the cut produce passes under a fresh-water rinse, goes into a shaker, and then goes into a dryer basket. From the dryer basket, the cut produce is metered onto a conveyer system where it is conveyed up to a scale. The cut produce is weighed and bagged. The bag is sealed and then run through a metal detector. Once the bagged, processed produce passes through the metal detector, it is boxed, labeled, palletized, and moved into the finished goods storage room. The Petitioner then stores the finished product until its employees load the product onto the Petitioner's refrigerated trucks for delivery to the consumer.

Supplies at Issue

1. Protective Clothing: Gloves, Aprons, and Hairnets.

The Petitioner requires its employees to wear protective clothing in both the low-care and the high-care areas. The Petitioner requires its employees to wear more protective clothing, such as overshoes and smocks,[6] in the high-care area because this is the area where produce is cut and exposed to the environment. The Petitioner's annual budget for purchasing protective clothing for its employees is approximately $100,000 - $150,000 per year. Most of the protective clothing are single use items. Federal law requires produce-processing plants, like the Petitioner's, to develop "good manufacturing practices," which must include the requirement that employees wear certain protective clothing for food safety purposes.

Wayne Bailey, the Petitioner's current food safety director, testified that the Petitioner's "good manufacturing practices," which are set forth in Petitioner's Exhibit 18, requires the wearing of appropriate apparel so that a person in street clothes and street shoes will not or should not come into contact with food-contact surfaces or the produce. In so doing, the Petitioner is protecting the produce from anything that would come from outside the plant. The Petitioner's food safety expert,

[6]Overshoes and smocks are not included in the category of protective clothing at issue in this case.

Dr. David Gombas, testified that the sources of contaminants, or harmful microorganisms, are the employees, the water used in the facility, and the raw produce. The protective clothing protects the produce from the Petitioner's employees. Specifically, it prevents any microbiological contaminants that may be present on the employee from getting into the final product. Protective clothing also helps minimize cross contamination or the spreading of pathogens that may already be present. Ultimately, the purpose of the protective clothing is to protect the consumer by preventing the Petitioner's final product—a food item—from being contaminated with harmful microorganisms.[7]

As stated above, the Petitioner's employees must wear more protective clothing in the high-care area. However, the protective clothing at issue—gloves, aprons, and hairnets—is worn in both the low-care and high-care areas.[8] The Petitioner considers its high-care area to be a clean room. The Petitioner further claims that the protective clothing at issue is required to be worn in a clean room. Tom Lovelace, the Petitioner's executive Vice President, testified that "[e]ach of the air handling units has filtering that filters air to .3 microns. The compressed air that's used to help package the product is filtered to .1 microns." According to Mr. Lovelace, that means the Petitioner has a clean room. Mr. Bailey testified that the Petitioner is audited by the British Retail Consortium (the "BRC") every year, and the BRC auditor looks at the Petitioner's "clean room environment." Mr. Bailey could not say that the BRC certified that the Petitioner had a clean room, though. In fact, none of the Petitioner's witnesses could point to a document certifying that it had a clean room.

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[7]Even the Petitioner's protest letter explains that the purpose of the protective clothing is to protect the produce.

[8]The Petitioner does not maintain any records showing the percentage of protective clothing worn in the high-care area versus the low-care areas.

A review of the 2015 BRC audit report, Petitioner's Exhibit 11, does not mention anything related to whether the Petitioner has a clean room. The report does discuss filtering air, but not in the way the Petitioner's witnesses represented. The report states on page 34 that the "[c]ompressed air used on product contact surfaces is filtered to 0.5 micron." Mr. Lovelace testified the compressed air, which the Petitioner uses when bagging the product, was filtered to .1 microns. Also on page 34, section 4.413 discusses filtered air in high-risk areas and states this requirement is not applicable to the Petitioner. Thus, it appears the BRC auditor did not evaluate the air filtration in the Petitioner's plant. Assuming the BRC auditor did evaluate the air filtration in the plant, the BRC auditor did not determine whether the high-care area is a Class 100 or better as defined in Federal Standard 209E clean room environment, nor did it audit the Petitioner's facility against the Federal Standard 209E clean room requirements.[9] It is apparent that the role of a BRC auditor is not to determine whether a food processing plant has and properly maintains a clean room, but rather to determine whether the plant meets the BRC's standards. In sum, the BRC report contains nothing regarding whether the Petitioner has a Class 100 or better as defined in Federal Standard 209E clean room environment.

2. Floor Drain Covers.

The Petitioner installs floor drain covers inside its facility to keep debris from entering the floor drain system. The Petitioner uses the floor drain system to recapture spilled water so it may reuse the water to wash the produce.

3. Warning Signs and Stickers.

Throughout the facility the Petitioner uses warning signs and stickers to warn employees about certain hazards and to remind employees about certain procedures. Approximately 80% of

[9]Moreover, none of the Petitioner's witnesses could identify all the requirements for qualifying as a Class 100 or better as defined in Federal Standard 209E clean room environment.

the Petitioner's warning signs and stickers are used in what the Petitioner describes as the manufacturing or processing area of the facility, as opposed to an administrative area. However, the Petitioner does not maintain records delineating where or how it uses different warning signs and stickers.

4. Blower Fan.

The Petitioner maintains the temperature in the facility, excluding the administrative areas, between 33 – 40 degrees. As part of the process the Petitioner uses to maintain the temperature, the Petitioner uses blower fans to move refrigerated air throughout the plant.

5. Storage Supplies: Warehouse Racks and Stacking Containers.

The Petitioner uses different types of warehouse racks and containers for storage: flow-through racks, a pushback rack system, and stacking containers. It uses flow-through racks in the storage coolers where palletized raw produce flows through from one side to the other. It also uses a pushback rack system where it places raw produce or finished product onto a carriage that is pushed back or up and out. The warehouse racks help with efficiency and keeping the produce separated. The warehouse racks enable the Petitioner to maintain the temperature of the produce during storage.

The Petitioner also uses stacking containers for storage. When a customer orders more than one product, the product that is finished first must be stored until the other products are finished. The Petitioner uses stacking containers for said storage. For example, a customer may order cabbage made into coleslaw with a separate bag of carrots. In fulfilling that order, the Petitioner would first make separate bags of carrots and place them in the stacking containers. Then the Petitioner would make the bags of cabbage and place them in a master case. Once the master case is filled with bags of cabbage, the Petitioner moves the bags of carrots from the

stacking containers to the master case, seals, labels, and palletizes the case, and then stores the case in the finished goods storage area.

6. Material Handling Supplies: Forklift Batteries, Forklift Parts, Forklift Repair Parts, Forklift Rentals, Pallet Jacks, and Oil Lubricant for Handtrucks and Pallet Jacks.

The Petitioner uses forklifts and pallet jacks to move product from place to place within the facility. However, none are used from the time the first processing machine—the cutter—is fed through the time the final product is discharged from the packing machine. These supplies are mostly used in the palletizing, shipping, finished storage, raw storage, tomato repack, and receive dock areas of the facility to move produce before or after it is processed. The Petitioner does not track where it uses each item.

7. Generator Rental.

The Petitioner rents ethylene generators to speed up the ripening process, which takes place in the tomato cooler area. Tomatoes arrive at the facility in various color stages, and different customers have different color requirements. When necessary, the Petitioner rents generators to speed up the ripening process to get the tomatoes to the color required by the customer.

8. Bar Code Scanners.

A bar code scanner is a hand-held device that the Petitioner uses to read bar codes. Pursuant to Federal law, the Petitioner must be able to trace the product back one step to the grower-shipper and forward one step to the customer's distribution center.[10] As part of the tracing process, the Petitioner uses the bar code scanner to scan the bar code on the product when it enters the facility, when it goes into processing, when it goes to the finished goods storage area, and finally when it goes onto the refrigerated truck.

[10]Mr. McEntire testified that the need for a trace-back arises when a food-borne illness results in sickness or death and the FDA needs to determine the source of the illness.

9. Black Ink Aerosol Cans.

The Petitioner uses black ink aerosol cans when it labels finished cases. Specifically, the ink goes across a jet ink sprayer to spray a "use-through code" and a "lot code" onto the corrugated box. The lot codes assist in the trace-back process.

10. Cleaning Machines—Foamers.

Every night, the Petitioner utilizes cleaning machines, called foamers, to sanitize the processing equipment in the high-care area. The Petitioner did not provide any evidence regarding the specific "processing machines" it cleans with the foamers, whether such cleaning is necessary to ensure the functioning of the equipment, or whether such cleaning ensures that the quality of the product is maintained.

11. Maintenance Tools and Cut Wheel and Disc Maintenance Tools.

The Petitioner uses maintenance tools to maintain, repair, install, and uninstall equipment. The Petitioner uses these tools anytime a machine breaks down in any part of the plant. The cut wheel and disc maintenance tools are used specifically on the cut wheels and discs on the cutting machines.

12. Cleaning Supplies: Brooms, Floor Treatment Chemicals, and Squeegees.

The Petitioner uses different supplies to keep its plant clean. The Petitioner uses brooms to sweep debris off the floor and sometimes off the storage racks, floor treatment chemicals to sanitize the floor primarily in the high-care area, and squeegees to move debris and water off the floor into drains in the high-care area and the raw cooler area. These supplies have no purpose other than to sanitize the facility. These supplies may also be used in the administrative areas of the facility. The Petitioner does not keep records delineating where or how it uses each cleaning supply.

13. Mobile Computer Stand.

The Petitioner uses a computer program to track its produce processing operation. The computers are placed on a mobile computer stand in various parts of the facility so the employees can track the process as the produce moves through the facility.

14. White Boards in Production Offices.

The Petitioner uses white boards to track production efficiency and production yield. For example, employees receive a bonus depending on how fast they produce sliced tomatoes. The white board is used to track the employees' progress.

15. Storage Water Tanks.

The Petitioner has two storage water tanks. One tank is located under a roof outside the refrigerated portion of the facility. The Petitioner uses this tank to mix sanitation chemicals with chilled water, which is later pumped into the high-care area for washing the produce. The second tank is located inside the high-care area and is used to recirculate the cleaning water.

The Department's Audit and Subsequent Events

The Department audited the Petitioner's sales and use tax returns for tax periods October 1, 2012 through September 30, 2015. On July 19, 2016, after reviewing the Petitioner's purchase invoices and discussing questionable items with the Petitioner, the Department mailed and emailed the Petitioner the Proposed Assessment holding the supplies at issue purchased during the Audit Period as taxable. The Department included the entire Audit Period in the Proposed Assessment pursuant to S.C. Code Ann. § 12-54-85(C)(3) (Supp. 2017), which provides for a seventy-two (72) month statute of limitations when "there is a twenty percent understatement of the total of all taxes required to be shown on the return or document."[11] Logan Mitchell, the Department's auditor in

[11]The section of the Proposed Assessment entitled "EXCEPTION TO TIME LIMITATION FOR ASSESSMENT OF TAXES" provided that "[p]er S.C. Code section 12-54-

this case, testified that the Petitioner's lowest percentage of understatement for any given period during the Audit Period was three-hundred and twenty-seven (327) percent, which is significantly greater than twenty (20) percent. Based on that understatement, the Department determined that it had seventy-two (72) months, not thirty-six (36) months, to issue the Proposed Assessment.

Shortly after the Department emailed the Petitioner's accountant a copy of the Proposed Assessment, the Petitioner's accountant replied, stating he believed the statute of limitations expired on a portion of the audit. The Department responded to the Petitioner's accountant and explained that because the Petitioner understated the tax due by more than twenty (20) percent during each period of the Audit Period, the seventy-two (72) month statute of limitations period applied, not the thirty-six (36) month period. The Department did not receive any additional correspondence from or on behalf of the Petitioner regarding the statute of limitations.

The Petitioner timely protested the Proposed Assessment on August 1, 2016, but did not raise the statute of limitations issue. The Petitioner supplemented its protest letter on September 23, 2016, which also failed to address the statute of limitations issue. The parties held a conference but could not resolve all the issues. On February 7, 2017, the Department issued its Determination finding that the following purchases the Petitioner made during the Audit Period were subject to sales and use tax: (1) electricity used to refrigerate produce before and after said produce is processed; (2) certain supplies, including those listed under "Exhibit A" above; and (3) safety attire/protective clothing. The Petitioner timely requested a contested case hearing on March 7, 2017. Prior to the hearing in this matter, the parties resolved the issues related to the Petitioner's purchases of electricity and all supplies except the thirty-five (35) supplies listed under "Exhibit

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85, the time limitation did not apply to this audit since the taxpayer had a 20% understatement of the total of tax required to be shown on all periods under the audit. The taxes in this case may be assessed at any time within 72 months from the date of the first period under audit."

A" above.

CONCLUSIONS OF LAW

General Conclusions

This Court has subject matter jurisdiction in this case pursuant to S.C. Code Ann. §§ 1-23-600(A) (Supp. 2015) and 12-60-460 (2014). The hearing before the ALC is a contested case hearing and is heard de novo. Marlboro Park Hosp. v. S.C. Dep't of Health and Envtl. Control, 358 S.C. 573, 579, 595 S.E.2d 851, 854 (2004). This Court must make its factual findings based on the preponderance of the evidence. See S.C. Code Ann. § 1-23-600(A)(5) (Supp. 2015); see also Anonymous (M-156-90) v. State Bd. of Med. Exam'rs, 329 S.C. 371, 375-78, 496 S.E.2d 17, 19-20 (1998); Nat'l Health Corp. v. Dep't of Health and Envtl. Control, 298 S.C. 373, 379, 380 S.E.2d 841, 844 (Ct. App. 1989). Because the Petitioner is challenging a determination by the Department that the Petitioner's purchases of the supplies at issue are subject to sales and use tax, the Petitioner has the burden of proof. See Ford v. Atl. Coast Line R. Co., 169 S.C. 41, 168 S.E. 143, 167 (1932) ("The general rule is, in the absence of valid statutory enactment to the contrary, that the burden of proof rests upon him who has the affirmative of the issue"); see also Leventis v. Dep't of Health and Envtl. Control, 340 S.C. 118, 132-33, 530 S.E.2d 643, 651 (Ct. App. 2000). This burden requires the Petitioner to prove that the Department's determination is errant by a preponderance of the evidence. See, e.g., Janasik v. Fairway Oaks Villas Horizontal Prop. Regime, 307 S.C. 339, 346, 415 S.E.2d 384, 388 (1992) ("Findings of fact based upon a 'preponderance' of the evidence are those supported by the greatest 'weight, amount, credibility or truth' as reflected by the whole of the evidence before the court, or 'evidence which convinces as to its truth.'").

Applicable Law

It is well-settled law that absent an exemption from use tax, a use tax is imposed on a taxpayer's "storage, use, or other consumption in this State of tangible personal property purchased

at retail for storage, use, or other consumption in this State . . . ." S.C. Code Ann. § 12-36-1310(A) (2014). Moreover, the taxpayer claiming the exemption has the burden to prove its right to the exemption by bringing itself clearly within the conditions imposed by the exemption. See TNS Mills, Inc., v. S.C. Dept. of Revenue, 331 S.C. 611, 618, 154 S.E.2d 471, 475 (1981).

I. S.C. Code Ann. § 12-36-2120(17)—The Machine Exemption

The Petitioner claims its purchases of the supplies at issue,[12] excluding the protective clothing, are exempt from use tax as machines or machine parts used in processing tangible personal property for sale pursuant to S.C. Code Ann. § 12-36-2120(17). I disagree. The proper test to determine whether a machine or a machine part is exempt from sales and use tax is to determine whether the machine or machine part is integral and necessary to the manufacturing process. See Spring Industries, Inc. v. S.C. Dept. of Revenue, Docket No. 99-ALJ-17-0153-CC (S.C. Admin. Law Ct. Nov. 9, 1999); see also Hercules Contractors and Engineers, Inc. v. S.C. Tax Comm'n, 280 S.C. 426, 313 S.E.2d 300 (Ct. App. 1984). S.C. Code Ann. Regs. 117-302.5 (2012) incorporates the aforementioned rulings and sets forth several tests to determine whether a machine or machine part is exempt.

For this Court to determine whether the Petitioner's purchases of the supplies at issue are exempt, the Petitioner, who has the burden of proof in this case, had to present evidence to the Court about the use and purpose of each of the items at issue. The Petitioner failed to present any evidence about the use and purpose of six of the items at issue: coveralls,[13] eyewear,[14] towels,

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[12]See "Exhibit A," supplies numbered 1 – 4 and 8 – 35.

[13]When the Petitioner's witnesses discussed protective clothing they only mentioned gloves, hairnets, and aprons. The witnesses never mentioned coveralls or eyewear, thus I cannot assume that coveralls and eyewear are included in the category of "protective clothing."

[14]See footnote 13.

plastic shelves for maintenance parts room, utility cart for maintenance tools, and drug test kits. Without evidence, the Petitioner cannot meet its burden of proving these supplies fall clearly within the conditions imposed by § 12-36-2120(17) (the "Machine Exemption"). Because the Petitioner presented no evidence about these supplies, I find that the Petitioner's purchases of coveralls, eyewear, towels, plastic shelves for maintenance parts room, utility cart for maintenance tools, and drug test kits are subject to use tax.

The Petitioner did present evidence regarding the use of the remaining supplies at issue. Thus, this Court must examine the evidence and determine whether the Petitioner's purchases of the remaining supplies fall clearly within the conditions imposed by the Machine Exemption. In doing so, this Court must determine whether the supplies at issue are integral and necessary to the manufacturing process at issue—processing produce. After applying Regulations 117-302.5(B)(2)-(10), which specifically address several of the supplies at issue, and Regulation 117-302.5(B)(1), which sets forth general guidance, to the facts in this case, I conclude that the Petitioner failed to prove that the supplies at issue are integral and necessary to processing produce. As such, I conclude that all the supplies at issue are subject to use tax.

A. Regulation 117-302.5(B)(4)—Conveyances.

Regulation 117-302.5(B)(4)(a) states:

> [M]aterial handling machinery [and their parts] . . . [are] subject to the tax up until the point where the materials go into process. The machine feeding the first processing machine(s) is exempt. The last machine to come within the exemption is that machine which discharges the finished product from the last machine used in the process. Material handling machinery used for transporting (in process) material from one process stage to another comes within the exemption. Warehouse machinery used only for warehouse purposes, loading and unloading, storing, transporting raw materials and finished products, etc., is subject to the tax [unless otherwise exempt].

I find that the Petitioner's material handling supplies (forklift batteries, forklift parts, forklift repair parts, forklift rentals, pallet jacks, and oil lubricant for handtrucks and pallet jacks) constitute conveyances and, thus, fall within Regulation 117-302.5(B)(4). A review of the evidence demonstrates the Petitioner only uses these material handling supplies for warehouse purposes to transport raw produce or finished product within the facility. The Petitioner presented no evidence that these supplies are used to feed the first processing machine or for transporting in process material. Accordingly, I conclude that the Petitioner's purchases of material handling supplies are subject to use tax.

B. Regulation 117-302.5(B)(5)—Chemicals.

Regulation 117-302.5(B)(5) provides that chemicals that are used in an exempt machine on an ongoing and continuous basis and are essential to the functioning of the exempt machine are exempt from use tax. Thus, chemicals that are used on a non-exempt machine, are not used on an ongoing and continuous basis, and/or are not essential to the functioning of an exempt machine are subject to use tax. The Petitioner uses floor treatment chemicals to sanitize the floor of the facility. The floor is not an exempt machine. Even if the floor was an exempt machine, the floor treatment chemicals are not essential to the functioning of the floor. As such, I conclude that the Petitioner's purchases of floor treatment chemicals are subject to use tax.

C. Regulation 117-302.5(B)(6)—Maintenance.

Generally, maintenance machines are not exempt from sales and use tax.

> Machines that [1] are used to maintain non-exempt machines (machines that are not integral and necessary to the manufacturing process), or [2] are not used on an ongoing, continuous basis to maintain exempt manufacturing machines (machines that are integral and necessary to the manufacturing process) are maintenance machines and are not exempt from the tax as machines used in manufacturing tangible personal property for sale.

Regulation 117-302.5(B)(6). Examples of non-exempt maintenance machines include cleaning machines used to clean non-exempt machines, cleaning machines that are not used on an ongoing and continuous basis to maintain an exempt machine, machines used to clean floors and other parts of realty, and machines used to clean an exempt machine when such cleaning is not essential to ensure the functioning of the exempt machine or that the quality of the product is maintained. Id. For reasons explained more fully below, I find that the Petitioner's foamers, maintenance tools, cut wheel and disc maintenance tools, and cleaning supplies (brooms, floor treatment chemicals, and squeegees) are non-exempt maintenance machines.

The Petitioner uses foamers—cleaning machines—every night to sanitize the processing equipment in the high-care area. Thus, the Petitioner established that the foamers are used on an ongoing and continuous basis to clean exempt machines. However, if such cleaning is not essential to ensure the functioning of the exempt machines or that the quality of the product is maintained, then the foamers are subject to the tax. A review of the record demonstrates that the Petitioner failed to prove whether the use of the foamers ensures the functioning of the processing equipment or that the quality of its product is maintained. Absent such evidence, I must find that the Petitioner failed to bring itself clearly within the conditions imposed by the Machine Exemption. As such, I conclude that the Petitioner's purchases of foamers are subject to use tax.

The Petitioner uses maintenance tools and cut wheel and disc maintenance tools to maintain, repair, install, or uninstall equipment only when a machine breaks down. Thus, the Petitioner does not use these tools on an ongoing and continuous basis. Accordingly, I conclude that the Petitioner's purchases of maintenance tools and cut wheel and disc maintenance tools are subject to use tax.[15]

[15]Additionally, the Petitioner failed to establish exactly on which machines it uses the general maintenance tools (the cut wheel and disc maintenance tools are used on the cutter—an

Finally, the Petitioner uses certain cleaning supplies—brooms, floor treatment chemicals, and squeegees—as part of its sanitization process. Specifically, the Petitioner uses these cleaning supplies to sanitize the floor of the plant. Additionally, the Petitioner may use the brooms to sweep debris off the storage racks. In that regard, I find the Petitioner uses these cleaning supplies as maintenance machines. Since the cleaning supplies are used to clean the floor and storage racks (non-exempt machines), the cleaning supplies are not integral and necessary to the manufacturing process. Accordingly, I conclude that the Petitioner's purchases of brooms, floor treatment chemicals, and squeegees are subject to use tax.

D. Regulation 117-302.5(B)(7)—Storage.

Regulation 117-302.5(B)(7) provides:

> Machines used at a manufacturing facility for storage are not exempt from the tax as a machine used in manufacturing tangible personal property for sale. For example, the following machines are for storage and therefore taxable: (a) Racks used to store raw materials or finished goods. (b) Storage tanks used to store raw materials, gasses, or water.

The Petitioner uses warehouse racks to store raw materials and finished goods. The Petitioner uses stacking containers to store a finished product until said product can be transferred into a master case with another finished product. Accordingly, I find that the warehouse racks and stacking containers are for storage, and therefore, I conclude that the Petitioner's purchases of warehouse racks are subject to use tax.

Additionally, the Petitioner has two types of storage water tanks. One type of tank of is used to mix sanitation chemicals with chilled water and hold the cleaning water until it needs to

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exempt machine). Absent evidence establishing the general maintenance tools are used on exempt machines, I must conclude that the Petitioner failed to meet its burden of proof. Thus, even if the Petitioner used the general maintenance tools on an ongoing and continuous basis, the Petitioner's purchases of general maintenance tools would still be subject to use tax.

be pumped into the high-care area. The second type of tank is used to hold recirculated cleaning water. I find that the second type of tank is used only for storage, and therefore, I conclude that the Petitioner's purchases of the second type of storage tank is subject to use tax. While the first type of storage tank may be exempt, the Petitioner failed to present evidence regarding the purchase cost attributable to each type of tank. Absent such evidence, I cannot determine which tank purchases, if any, are exempt. Therefore, because the Petitioner failed to meet its burden of proof, I conclude that all its purchases of storage water tanks are subject to use tax.

E. Regulation 117-302.5(B)(9)—Administrative.

Regulation 117-302.5(B)(9) provides that administrative items "such as office computers used for word processing, recordkeeping, employee payroll, customer billing, purchasing, accounting, and similar purposes, office furniture, office supplies, [and similar items] . . . are not machines used in the process of manufacturing tangible personal property for sale." The Petitioner uses mobile computer stands to hold the computers used to track the manufacturing process. The Petitioner uses white boards to also track the manufacturing process. I conclude that supplies used to track the manufacturing process are administrative items. Specifically, I find that an item used merely to track the manufacturing process is not an essential and indispensable component part of the manufacturing process. Said differently, the Petitioner can process produce—sort, cut, wash, and/or package it—without tracking said process. Therefore, I conclude that the Petitioner's purchases of mobile computer stands and white boards are subject to use tax.

Similarly, I find that the Petitioner's bar code scanners and black ink aerosol cans are administrative items. The Petitioner uses both items to trace from where the produce came and to where the finished product was delivered. This trace forward and trace back procedure amounts to a type of recordkeeping, which is an administrative task. Moreover, tracing the produce is not

essential to processing produce. The produce can be processed without knowing from where it came and to where it was delivered. As such, I conclude that the Petitioner's purchases of bar code scanners and black ink aerosol cans are subject to use tax.

F. Regulation 117-302.5(B)(1)—Machines Generally.

The general test, which is found in Regulation 117-302.5(B)(1), sets forth the following elements to determine whether a machine or machine part is integral and necessary *to the manufacturing process*, not just to the manufacturer: (1) The machine must be used at a manufacturing facility; (2) The machine must be used in and serve as an essential and indispensable component part of the manufacturing process; (3) The machine must be used on an ongoing and continuous basis during the manufacturing process; and (4) The machine must be substantially used in manufacturing tangible personal property for sale. The Regulation further provides that "more than one-third of a machine's use in manufacturing is substantial." After reviewing the remaining supplies at issue, I conclude that the Petitioner's purchases of such supplies are subject to use tax.

The Petitioner is a type of manufacturer that processes produce. Thus, the "manufacturing process" at issue is produce processing. The Petitioner failed to establish that the floor drain covers, warning signs and stickers, blower fans, and generator rentals are integral and necessary to processing produce. While the Petitioner established all these supplies are used at a manufacturing facility, satisfying the first element of the test, the Petitioner failed to establish that these supplies satisfy the remaining elements. In fact, the evidence demonstrates that some of the remaining supplies do not serve as an essential and indispensable component part of processing food, while others are not used on an ongoing and continuous basis during the food processing. When the Petitioner processes produce, it sorts, cuts, washes, and packages the produce. Thus, for

the remaining supplies to be exempt, the Petitioner must prove that the supplies serve as an essential and indispensable component part of processing produce, and that the supplies are used on an ongoing and continuous basis during the process.

The Petitioner uses floor drain covers to keep debris from entering the floor drain system, which is part of the Petitioner's process of recycling the cleaning water. Recycling the cleaning water is not essential to wash the produce as the Petitioner may, and actually does, pump in water to be used in cleaning the produce. Therefore, I conclude that the floor drain covers do not serve as an essential and indispensable component part of the manufacturing process, and the Petitioner's purchases of the floor drain covers are subject to use tax.

The Petitioner uses warning signs and stickers throughout the facility to warn employees about certain hazards and to remind employees about certain procedures. The produce can be sorted, cut, washed, and packaged without warnings. Accordingly, the warning signs and stickers do not serve as an essential and indispensable component part of the manufacturing process. While the warning signs and stickers may be integral and necessary to the Petitioner, they are not integral and necessary to processing produce. Therefore, I conclude that the Petitioner's purchases of warning signs and stickers are subject to use tax.

The Petitioner uses blower fans to move refrigerated air around the plant. Regulation 117-302.5(C)(24) states that "[m]achines used to condition air (including humidification systems) for quality control *during the manufacturing process* of tangible personal property made from natural fibers and synthetic materials" are exempt machines. The Petitioner's witnesses testified repeatedly about the importance of keeping the temperature in the plant between 33 and 40 degrees to reduce pathogen growth. The Petitioner's witnesses also testified that the blower fans contribute to keeping the plant temperature between 33 and 40 degrees. However, the exemption only applies

to machines used during the manufacturing process, which in the Petitioner's plant only occurs in the cutting room, tomato repack room, and pack-out room. Accordingly, for the blower fans to be exempt, they would have to be substantially used in the cutting room, tomato repack room, and/or pack-out room. The Petitioner did not provide any evidence regarding where each blower fan was used. Absent such evidence, I cannot determine that any blower fan was used substantially during the manufacturing process.

Additionally, the exemption for machines used to condition air only applies to tangible personal property made from natural fibers and synthetic materials. The Petitioner turns raw produce into a finished product, such as chopped lettuce. In that sense, the Petitioner does not *make* anything. Moreover, the Petitioner presented no evidence that its final products are made from natural fibers and synthetic materials. While the finished product may consist of natural fibers, the Petitioner did not take natural fibers and make a finished product. Assuming, however, I found the Petitioner did take natural fibers—a raw head of lettuce—and make a finished product—chopped lettuce, the regulation uses the word "and" not "or." Thus, the Petitioner would have had to make the chopped lettuce out of a raw head of lettuce *and* synthetic materials. The Petitioner presented no evidence demonstrating it uses any synthetic material to turn raw produce into a finished product. Thus, because the Petitioner failed to prove it uses the blower fans substantially during the manufacturing process and that it makes a product from natural fibers and synthetic materials, I conclude that the Petitioner's purchases of blower fans are subject to use tax.

Finally, the Petitioner rents ethylene generators on an as-needed basis to speed up the tomato ripening. Using a machine "as needed" does not constitute ongoing and continuous use. Tomato ripening is part of the tomato repack operation. Mr. McEntire testified that there are times when the tomatoes are so unripe that the ripening process needs to be sped up. It is on those

occasions that the Petitioner rents the generators. Ordinarily, the tomatoes are left in the tomato coolers to ripen. Accordingly, since ripening is part of the tomato repack operation, and thus, processing produce, any generators used on an ongoing and continuous basis during the ripening stage of the process could be exempt. However, I find that using a machine on an "as needed" basis does not constitute "ongoing and continuous." Thus, because the generators at issue here were not used on an ongoing and continuous basis, I conclude that the Petitioner's generator rentals are subject to use tax.

II. The Protective Clothing.

The Petitioner argues that its purchases of protective clothing—gloves, aprons, and hairnets—are exempt from use tax pursuant to S.C. Code Ann. § 12-36-2120(54) as "clothing and other attire required for working in a Class 100 or better as defined in Federal Standard 209E clean room environment" (the "Clean Room Exemption"). The Petitioner argues alternatively that its purchases of protective clothing are exempt from use tax pursuant to S.C. Code Ann. § 12-36-2120(17) as pollution control machines (the "Pollution Control Machine Exemption"). I disagree. As will be discussed below, the Petitioner failed to bring itself clearly within the conditions imposed by either exemption. As such, I conclude that the Petitioner's purchases of protective clothing are subject to use tax.

A. The Clean Room Exemption.

In order for the Petitioner to bring itself clearly within the conditions imposed by the Clean Room Exemption, the Petitioner had to prove that (1) the Petitioner has a Class 100 or better clean room as defined by Federal Standard 209E[16] and (2) the protective clothing at issue is required for

[16]Federal Standard 209E has been replaced with International Standards Organization (ISO) 14644-1. Nonetheless, the General Assembly has not changed the language of the statute. Thus, for the Petitioner to bring itself clearly within the conditions imposed by the Clean Room Exemption, it must prove it has a Class 100 or better clean room as defined by the Federal Standard.

working in the clean room. The Petitioner failed to present sufficient evidence to satisfy either element.

The Petitioner did not present a shred of evidence that it actually has within its facility a Class 100 or better clean room as defined by Federal Standard 209E. The Petitioner's witnesses all testified that the plant has something similar to a clean room. For example, Mr. Carter testified that the FDA requires the Petitioner to maintain a certain level of cleanliness, and those levels of cleanliness meet or exceed Class 100 standards. Thus, according to Mr. McEntire, any room that is clean enough could be a clean room if "you chose to call it that." Similarly, Mr. Bailey testified that the Petitioner uses the terms "high-care" and "clean room" interchangeably. He testified that with what the Petitioner does in the facility "it would be considered a clean room." Finally, Mr. Lovelace confirmed that the BRC does not audit whether the Petitioner's facility satisfies the clean room standards. The 2015 BRC report the Petitioner provided confirms Mr. Lovelace's testimony in that the report does not contain any determination or evaluation relating to whether Petitioner's facility contains a Class 100 or better clean room. In sum, the Petitioner presented no clear evidence regarding the clean room requirements or whether the high-care room is a Class 100 or better clean room as defined by Federal Standard 209E.

Assuming the Petitioner established it has something like a clean room, such is not sufficient for the Petitioner to meet its burden of proof. The Petitioner had to clearly prove that it has a Class 100 or better clean room as defined by Federal Standard 209E, not something similar. Moreover, in addition to proving it has a clean room, the Petitioner had to prove the protective clothing at issue is required to be worn in the clean room. Despite such requirement, the Petitioner only proved that the FDA requires certain protective clothing to be worn in a food processing plant to prevent the product from becoming adulterated. Accordingly, because the Petitioner failed to

prove that it in fact has a clean room as required by § 12-36-2120(54) and that the protective clothing is required to be worn in that clean room, I conclude that the Petitioner's purchases of protective clothing are not exempt from use tax pursuant to the Clean Room Exemption.

B. The Pollution Control Machine Exemption.

Section 12-36-2120(17) provides an exemption from sales and use tax for machines and its parts and attachments that "are necessary to comply with the order of an agency of the United States or of this State for the prevention or abatement of pollution of air, water, or noise that is caused or threatened by any machine used as provided in this section." S.C. Code Ann. Regs. 117-302.6 explains that a machine constitutes an exempt pollution control machine if such machine is "installed and operated for compliance with an order of an agency of the United States or of this state to prevent or abate pollution caused or threatened by the operation of other machines used in the . . . manufacturing of tangible personal property." Accordingly, the Petitioner had to prove that (1) the operation of at least one of its machines used in processing causes or threatens to cause pollution of air, water, or noise, (2) a State or Federal agency requires that the pollution be prevented or abated, and (3) the protective clothing is used to prevent or abate the pollution. Because the Petitioner failed to bring itself clearly within the Pollution Control Machine Exemption, I conclude that the protective clothing is not exempt from use tax.

The Petitioner argues that it requires its employees to wear protective clothing to prevent the spread of microbiological contaminants such as E. Coli, Listeria, and Salmonella, and therefore, the protective clothing constitutes a pollution control machine. As a threshold matter, protective clothing does not qualify as a machine according to Regulation 117-302.5(B)(10). Since protective clothing is not a machine, it can never be a "pollution control machine." Nonetheless, assuming for arguments sake that the protective clothing at issue are machines and that overgrowth

of microbiological contaminants constitutes pollution, a review of the evidence demonstrates that the processing machines do not cause or threaten to cause an overgrowth of microbiological contaminants. Rather, the contaminants enter the facility either on the raw produce or on the Petitioner's employees. The contaminants may grow, spread, and contaminate other products because of the processing environment (temperature, moisture, etc.), but not because of the machines used to process food. Thus, because the Petitioner failed to prove that a machine used in processing causes or threatens pollution of air, water, or noise, the Petitioner failed to bring itself clearly within the conditions imposed by the Pollution Control Machine Exemption.

Further, the evidence demonstrates that the protective clothing prevents the product from being contaminated by harmful microorganisms. The purpose of the protective clothing is not to prevent air, water, or noise pollution. Thus, the protective clothing is not actually used to prevent air, water, or noise pollution. Accordingly, even if the processing machines did cause or threaten pollution of air, water, or noise, the protective clothing does not prevent or abate such pollution.

Finally, the Petitioner failed to present any evidence that an order of a State or Federal agency requires the Petitioner to prevent or abate pollution created by the Petitioner's processing machines. The Petitioner only referenced the FDA's requirements related to "good manufacturing practices." While the Petitioner's witnesses testified that the FDA requires that the Petitioner's employees wear protective clothing and that the Petitioner implement measures to prevent food from being adulterated, they did not state that the FDA requires any type of pollution control. Absent evidence of a State or Federal order requiring that the Petitioner prevent or abate pollution caused by its processing machines, I must conclude that the Petitioner failed to meet its burden of proof. Thus, I conclude that the Petitioner's purchases of protective clothing are subject to use tax.

III. Statute of Limitations

The Petitioner argued at the hearing that part of the Audit Period, and thus the Proposed Assessment, falls outside the thirty-six (36) month statute of limitations period, and therefore, is time-barred. The Department responded by asserting that the seventy-two (72) month, not the thirty-six (36) month, statute of limitations period applies in this case pursuant to S.C. Code Ann. § 12-54-85(C)(3). The Petitioner then argued that the Department could not assert at the hearing that the seventy-two (72) month period applies because it did not state such in the Department's Determination. I conclude, for the reasons set forth below, that the Department could assert that the seventy-two (72) month period applies in this case, that it correctly asserted the seventy-two (72) month period applies, and that it issued the Proposed Assessment within the seventy-two (72) month period.

First, I find that, while not required to, the Department did address the statute of limitations in its Determination. The Determination addressed the sales and use tax periods from October 1, 2012 through September 30, 2015. By stating those were the tax periods at issue, the Department implicitly asserted that the entire Audit Period was at issue, and thus not time-barred. Moreover, the Petitioner did not protest the Proposed Assessment on the basis that a portion of the Audit Period was time-barred. The Department cannot address in a department determination every potential argument a taxpayer might make, nor does the Revenue Procedures Act (the "RPA") require such. See S.C. Code Ann. § 12-60-10 et. seq. (2014 & Supp. 2017). Rather, the RPA requires that a department determination use the information provided by the taxpayer in its protest and "explain the basis for the department's determination." S.C. Code Ann. § 12-60-450(E)(2)(b) (2014). Pursuant to § 12-60-450(B), a taxpayer's protest "**must** contain . . . (6) a statement outlining the reasons for the appeal, including law or other authority upon which the taxpayer relies

. . . ." (emphasis added). Because the Petitioner did not even mention in its initial protest letter or supplemental protest letter that part of the Audit Period was time-barred, the Department was not required to specifically address the statute of limitations in the Determination. In fact, by failing to raise the statute of limitations issue in its protest, the Petitioner arguably waived its right to raise the statute of limitations issue during the hearing in this case.

Next, I conclude that the seventy-two (72) month statute of limitations period applies here. Pursuant to S.C. Code Ann. § 12-54-85(A), "[e]xcept as otherwise provided in this section, taxes must be determined and assessed within thirty-six months from the date the return or document was filed or due to be filed, whichever is later." Section 12-54-85(C) provides that "[t]axes may be determined and assessed after the thirty-six month limitation if: . . . (3) there is a twenty percent understatement of the total of all taxes required to be shown on the return or document. The taxes in this case may be assessed at any time within seventy-two months from the date the return or document was filed or due to be filed, whichever is later." Thus, when there is a twenty (20) percent understatement of the total of all taxes required to be shown on the return, the seventy-two (72) month, not the thirty-six (36) month, statute of limitations applies.

In this case, the Petitioner filed zero returns for all periods during the Audit Period except for periods ending September 30, 2013, November 30, 2013, and April 30, 2015, when it paid $2.00, $2.00, and $642.00, respectively, in sales and use taxes. Ms. Mitchell testified that the lowest percentage of understatement for any given period during the Audit Period was 327%, which is significantly greater than 20%. Accordingly, I find the Petitioner understated the total of all taxes required to be shown on all its returns during the Audit Period by at least twenty (20) percent. Therefore, I conclude that the Department had seventy-two (72) months from the later of the dates the returns were filed or due to be filed to issue the Proposed Assessment.

Finally, I find the Department timely issued the Proposed Assessment for the Audit Period. The first return at issue was due on November 20, 2012 and the last return at issue was due on October 20, 2015. Seventy-two (72) months from November 20, 2012, is November 20, 2018, and seventy-two (72) months from October 20, 2015, is October 20, 2021. That means the Department had until November 20, 2018, at the latest, to timely issue the Proposed Assessment for the entire Audit Period. The Department initiated its audit in September 2015 and issued the Proposed Assessment for the Audit Period on July 19, 2016, well within seventy-two (72) months from the date the returns at issue were due. Accordingly, I find that the Department timely issued its Proposed Assessment for the Audit Period and, therefore, the entire Audit Period is properly before this Court.

CONCLUSION

After considering the evidence in the record and the pertinent legal authorities, I conclude, based upon the reliable evidence, that all the Petitioner's purchases during the Audit Period of the supplies and protective clothing discussed herein are subject to use tax. I reject the Petitioner's argument that its manufacturing process begins when the raw produce arrives at the facility and ends when the finished product is loaded onto its refrigerated trucks. I also reject the Petitioner's arguments that its purchases of protective clothing are exempt from use tax as clothing required to be worn in a Class 100 or better clean room as defined by Federal Standard 209E or as pollution control machines.

ORDER

IT IS THEREFORE ORDERED that the Petitioner be assessed $82,305.83 in tax plus applicable interest.

IT IS FURTHER ORDERED that the Petitioner remit the $18,636.19 in tax due on the

items the Petitioner agreed were taxable prior to the hearing plus interest within thirty (30) days of the date of this Order.

AND IT IS SO ORDERED.

H.W. Funderburk
Administrative Law Judge

_____, 2019
Columbia, South Carolina

Respectfully submitted,

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Attorneys for Respondent

Charleston, South Carolina
January 7, 2019

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

McEntire Produce, Inc.,	)	Docket No. 17-ALJ-17-0060-CC
	)	
Petitioner,	)	
	)	
vs.	)	**PROOF OF SERVICE**
	)	
South Carolina Department of Revenue,	)	
	)	
Respondent.	)	
	)	

The undersigned hereby certifies that she served a copy of the Respondent's Proposed Final Order and Decision in the above-referenced case on the Petitioner's counsel on the date and at the address listed below by depositing a copy in the United States Mail, postage paid:

Burnet R. Maybank, III
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January 7, 2018
Charleston, South Carolina

NEXSEN | PRUET

Burnet R. Maybank, III
Member
Admitted in SC

January 7, 2019

VIA U.S. MAIL AND EMAIL
The Honorable H.W. Funderburk, Jr.
South Carolina Administrative Law Court
1205 Pendleton Street, Suite 224
Columbia, SC 29201

Re: McEntire Produce, Inc. v. South Carolina Department of Revenue
Docket No. 17-ALJ-17-0060-CC

Dear Judge Funderburk:

Enclosed please find the original and one copy of Petitioner's Proposed Order together with Certificate of Service. We also emailed Word and PDF copies to Julia Miller today. Kindly file the original and return the clocked copy in the postage-paid return envelope provided.

Thank you for your attention to this matter.

Very truly yours,

Burnet R. Maybank, III

BRM/mw

Enclosure – Petitioner's Proposed Order

cc: Lauren Acquaviva, Esq.
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STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

McEntire Produce, Inc., Petitioner, vs. South Carolina Department of Revenue, Respondents.	Docket No.: 17-ALJ-0060-CC **PETITIONER'S PROPOSED ORDER**

I. INTRODUCTION

This matter is before the South Carolina Administrative Law Court on request for a contested case hearing filed by McEntire Produce, Inc., under S.C. Code Ann. §12-60-460 (Supp. 2017). Petitioner challenges the Department of Revenue's Determination that Petitioner is not entitled to several sales tax exemptions.

Petitioner is taxed and classified as a manufacturer. Petitioner alleges the Department misapplied three manufacturer sales tax exemptions with respect to the audit. First, Petitioner alleges the Department applied the machine exemption found in S.C. Code Ann. § 12-36-21210(17) too narrowly in light of the specialized, climate-controlled, and highly regulated nature of Petitioner's food produce processing operations. Second, Petitioner contends the Department has failed to recognize the sales tax exemption available under § 12-36-2120(54) for the "clean room environment" which Petitioner maintains in its production facility. Finally, Petitioner contends that the pollution control exemption found in 12-36-2120(17) applies to purchases of overshoes, boot covers, sanitized smocks, eyewear, coveralls, eyewear, gloves, bump capws, hairnets, beard covers, and aprons (hereinafter collectively referred to as "protective clothing")

designed to ensure that Petitioner's operations do not spread harmful contaminants like E. coli, salmonella, and listeria onto both the finished product and facility outflow.

A hearing was held before the Court on November 14 and 15, 2018.

II. FINDINGS OF FACTS

The parties entered into Stipulations of Fact, which are incorporated herein by reference. In addition, having taken evidence and observed the witnesses and exhibits presented at the hearing and having taken into consideration the burden of proof and the credibility of witnesses, the Court makes the following findings of fact by a preponderance of the evidence:

A. Petitioner's Operations

Petitioner operates in the specialized and highly-regulated arena of fresh food processing. During the periods at issue, Petitioner's production primarily involved lettuce, onions, cabbage, tomatoes, and other vegetables.

Petitioner's "processing" includes receiving, storing, washing, cutting, mixing, and then packaging the produce at its facility. Petitioner called several witnesses who described its fresh food processing in depth. This production process is critical to reduce or eliminate harmful contaminants because the ultimate customer who eats the fresh produce does not take any preventive steps such as microwaving or cooking the produce to the extent necessary to kill or eliminate any contaminants.

Petitioner's process begins prior to the raw agricultural commodity even entering the facility. Petitioner contracts with a grower to harvest the product when it is about 80-85 degrees, so the first step in the process it to pull the heat from the produce, so that the temperature of the produce is reduced to below 40 degrees within no more than four hours from the time of harvest. This cooling step is essential to Petitioner's process because it slows the respiration rate of the

produce, thereby slowing the natural chemical process of ripening in the fruit and/or vegetable. It also minimizes microbiological growth rate. If the produce is not cooled immediately, then it risks turning brown, soggy, slimy, and inedible. Petitioner is required by state and federal regulation, as well as customer requirements, to track the produce as soon as it is loaded into its climate-controlled trucks. Petitioner must be able to demonstrate that the temperature on those trucks was between 33 and 40 degrees. Petitioner's customers (primarily large restaurant chains) have extensive contractual requirements in this regard.

As soon as the product is unloaded, it enters one of six raw coolers, which also are controlled at 33-40 degrees. Soon thereafter, the produce goes through the Ready to Eat ("RTE") process, where it is sorted, physically inspected, trimmed by hand to remove imperfections or browning, and then conveyed to an industrial cutter that discharges into a flume for washing. Petitioner's flume is a stainless steel bath that utilizes a water-based product to rinse and sanitize the product. The produce is washed a number of times before it moves to the next step. After washing, the produce goes through a "de-watering" step, which is essentially an industrial-sized salad spinner. This process of washing and de-watering is done in an effort to remove any pollutants or contaminants which were in the produce at the time of delivery to Petitioner.

The low care area is generally is reserved for whole produce, for example whole tomatoes, and involves their ripening, sorting, defect removal, and repackaging but no cutting of the produce. The physical cutting of produce releases pollutants, which are present on the produce at the farm level, and allows them to grow, multiply and spread which is the reason for the high care area.

The high care area is reserved for produce that is cut down to a smaller size. In the high care area, employees are required by state and federal law to wear protective clothing. The employees must also go through a specialized sanitization procedure to limit the introduction of

microbes to the high care area. The room is also positive-pressurized to ensure there is an outflow, as opposed to an inflow, of air. That pressurization, as well as filters for both ambient and compressed air touching the produce used to filter the air down to 0.1 microns, help maintain the cleanliness of the environment. The overall purpose of these procedures are to protect the produce from human contact and microbial loads. This protective clothing is required by state and federal law to prevent employees from accidentally bringing pollutants (chiefly E. coli) from their clothing into the high care area.

In the high care area, the produce is de-watered in a centrifugal dryer and moved on a conveyor belt to a scale, weighed and bagged, and then boxed and labeled for shipping. In the area, Petitioner is required by state and federal law and customer contractual requirements to meet exacting cleanliness standards to ensure the finished product is both free from harmful microbial growth and meets the stringent standards of its many customers. The high care meets the filtration requirements of a Class 100 Clean Room environment, which is confirmed by BRC, an independent auditing firm, on an annual basis.

Once bagged, boxed, and labeled, the produce is stored for an extremely short period of time in a refrigerated cooler, given the fresh nature of its cut produce, and is then shipped on climate-controlled trucks to its customers. Petitioner's customers are primarily large restaurant chains who put the fresh produce on salad bars and into hamburgers, sandwiches, etc. without any additional processing for health purposes, e.g., the produce is not cooked. Petitioner's customers also can track the extent to which the produce was kept in a climate-controlled area. For example, if the produce is stored for a period of time above 40 degrees, then the customer can simply reject the shipment. Further, to the extent the Food and Drug Administration (or a customer) on audit determined that the produce spent a period of time outside the temperature "safe zone," Petitioner

could be subject to reprimand, fines, or even plant closure, based on the severity of the violation. Petitioner is annually audited by the FDA in this regard. This means temperature and environmental controls permeate the entire production process, from the time the produce is delivered from the farm until the finished product leaves Petitioner's facility.

As stated below, this production process is designed to prevent foodborne illnesses. Some of the worst outbreaks of such illnesses have occurred in the past few years.

As detailed below, many of the items at dispute in this audit relate to Petitioner's attempt to combat three potentially serious foodborne microbes – Listeria monocytogenes, E. coli and salmonella. The microbes are described as follows:

- **Listeria monocytogenes** is a germ that can cause a serious infection called Listeriosis, which presents as flu-like symptoms. People usually become ill with listeriosis after eating contaminated food. The disease primarily affects pregnant women, newborns, older adults, and people with weakened immune systems. Approximately 80% of those with Listeriosis go into the hospital, and as many as 18% of those infected die.
- **Escherichia coli** (abbreviated as E. coli) are bacteria that can cause diarrhea, urinary tract infections, respiratory illness and pneumonia, and other illnesses. E. coli are pathogenic, meaning they can cause illness, either diarrhea or illness outside of the intestinal tract. The types of E. coli that can cause diarrhea can be transmitted through contaminated water or food, or through contact with animals or persons.
- **Salmonella** is a bacteria that can cause diarrhea, fever, and abdominal cramps between 12 and 72 hours after infection. The illness usually lasts 4 to 7 days. In some cases, diarrhea may be so severe that the patient needs to be hospitalized. In these patients, the Salmonella infection may spread from the intestines to the blood stream, and then

to other body sites. In these cases, Salmonella can cause death unless the person is treated promptly with antibiotics. The elderly, infants, and those with impaired immune systems are more likely to have a severe illness. See The Centers for Disease Control and Prevention website, available at www.cdc.gov.

All three microbes grow naturally in South Carolina and are present in farms across the country where Petitioner's produce is harvested. The germ and bacteria can breed in produce if the environment is conducive to that growth. Petitioner deals with these pollutants in two scenarios: (1) to prevent the spread of contaminants which are in produce delivered to its facilities; and (2) to prevent employees from introducing such pollutants into the facility from their own clothing and shoes.

At issue are three sales tax exemptions including the machine exemption. The Department contested the machine exemption for the following machinery and equipment:

(1) **Bar Code Scanner and Mobile Computer Stand**. The scanners are used to track all produce through the manufacturing process. Per Petitioner's procedures and to comply with federal rules, the produce is scanned (1) when the produce exits the truck; (2) when it enters the cutting area; (3) when it leaves the cutting area; and (4) when the finished goods enters the truck. This is a federal requirement so that the produce can be tracked (1) back to the farm, and (2) forward to the customer in the event contamination is subsequently found in the produce. The mobile computer stands are used by quality technicians, food safety technicians, and production operators, and assist in the scanning and tracking of Petitioner's process flows

(2) **Forklift, Forklift Parts, Forklift Repair Parts, Forklift Rentals, and Forklift Batteries**. Forklifts are used through the cutting process to move 800 lbs. to 1,600 lbs. bags of raw produce onto the conveyor belt at the beginning of the cutting area. While some of these forklifts are used

temporarily in other areas of Petitioner's operations, at least 1/3 of the use is related to moving produce to the cutting area.

(3) **Warehouse Racks.** These racks are specially designed to assist in cooling and maintaining the temperature of the raw produce and finished product. Pallets cannot be stacked on top of each other due to cooling limitations of the produce. The racks are galvanized, to withstand the cold, wet, and humid area.

(4) **Pallet Flow Brakes.** These brakes are used on the racks, which hold thousands of pounds of raw produce and finished product. The racks, which transport the produce into the cutting area, are potentially dangerous without the brakes.

(5) **Storage Water Tanks.** The water tanks are part of the produce wash process, which occurs in the middle of the cutting process. The tanks are part of a self-contained wash process.

(6) **Generator Rentals for Fruit Ripening Purposes.** During the audit period, Petitioner rented generators to power machines used to ripen the tomatoes to a color acceptable to its customers.

(7) **Hand Trucks and Pallet Jacks, and Oil Lubricants Used Therein.** The majority of the use of the hand trucks and pallet jacks are to move sliced tomatoes and sack onions from the cold storage area to the high care to the in-feed line for the cutting process.

(8) **Black Ink for Aerosol Cans.** The ink is used in the ink jet printers which print "Sell By" dates on the finished produce packaging.

(9) **Floor Drain Covers.** Stainless steel floor drain covers are used in the high care area and serve as both a filter and drain. Petitioner utilizes these higher-quality drains in its recycling of the wash water. These drains were selected because material previously was entering the closed wash water system, causing adulteration of the water.

(10) **Plastic Shelves Used in the Lab/Retained Sample Room.** Petitioner holds back at least one bag of each production run and places it on the plastic shelves of the refrigerated area. In the event a customer claimed their product did not last, Petitioner utilized the withheld produce as a control.

(11) **Floor Treatment Chemicals, Brooms, Squeegees, Cleaning Machines.** The floor treatment chemicals inhibits growth of dangerous microbes, and the brooms and squeegees are used specifically in those areas to inhibit such growth. Respondent agreed 70% of the floor treatment chemicals and other products were used in the manufacturing process, but contended that 30% was not. Petitioner testified that the vast majority of the floor treatment chemicals, brooms, and squeegees were used in the manufacturing process.

(12) **Stacking Containers.** Mr. McEntire testified the stacking containers are used in the "work in process" section of the facility to separate processed produce until it is combined. The combination of those products into a bag completes the manufacturing process with respect to those mixed products. Thus, the stacking containers which hold the component pieces of the finished product are an indispensable part of the process by transferring the product along the process.

(13) **Maintenance Tools and Utility Cart.** Mr. McEntire testified the vast majority of the maintenance tools are used to repair machines within the high care area. Moreover, according to Mr. McEntire, utility carts used within the manufacturing area require special care due to the sensitive nature of the high care environment.

(14) **Blower Fan**. Mr. McEntire testified the blower fans are used to circulate refrigerated air throughout the facility, including both the high care and low care areas. Without the blower fans, Petitioner could not maintain the required temperature in its facility.

The Proposed Assessment also contained as taxable cut wheels, discs and nylon slings; refrigerator for self-life processing and lamps but the DOR conceded this equipment qualified as exempt machinery during the trial. The parties also resolved the taxation of electricity, which was part of the original Proposed Assessment. After resolving these issues, the Petitioner and Respondent were able to reduce the amount of sales tax at issue to $82,305.83 plus interest.

III. CONCLUSIONS OF LAW

Based upon the above Findings of Fact, the Court concludes the following as matters of law. The ALC has jurisdiction to hear this contested cases pursuant to S.C. Code Ann. §§ 1-23-600 (Supp. 2017) and 12-60-460.

Burden of Proof and Standard of Review

The standard of proof in this administrative proceeding is a preponderance of the evidence. See *Anonymous v. State Bd. of Med. Exam'rs*, 329 S.C. 371, 496 S.E.2d 17 (1998). In general, the party asserting the affirmative issue in an adjudicatory administrative proceeding has the burden of proof. See *Leventis v. S.C. Dep't of Health & Envtl. Control*, 340 S.C. 118, 133, 530 S.E.2d 643, 651 (2000) (citing 2 Am. Jur. 2d Admin. Law §360 (1994)). Here, Petitioners requested a contested case hearing and, therefore, have the burden of proof to show by a preponderance of the evidence that the Department's tax assessments for the periods at issue were incorrect.

A. Machine Exemption (12-36-2120(17))

1. All machines used within the temperature-controlled portion of the facility are exempt as machines used in the manufacturing process.

S.C. Code Ann. § 12-36-2120(17) exempts from sales tax the sale of "machines used in manufacturing, *processing, agricultural packaging*, recycling, compounding, mining, or quarrying tangible personal property for sale" (emphasis added). "Machines," according to the exemption, "include the parts of machines, attachments, and replacements used, or manufactured for use, on

or in the operation of the machines and which ... are necessary to the operation of the machines and are customarily so used."

In applying these statutes, "[t]he cardinal rule of statutory interpretation is to determine the intent of the legislature." *Jones v. State Farm Mut. Auto. Ins. Co.*, 364 S.C. 222, 230, 612 S.E.2d 719, 723 (2005). Furthermore, "[t]he legislature's intent should be ascertained primarily from the plain language of the statute." *State v. Landis*, 362 S.C. 97, 102, 606 S.E.2d 503, 505 (Ct. App. 2004). "What a legislature says in the text of a statute is considered the best evidence of the legislative intent or will." *Bayle v. S.C. Dep't of Transp.*, 344 S.C. 115, 122, 542 S.E.2d 736, 740 (Ct. App. 2001). "Revenue laws are generally construed in favor of the taxpayer and against the taxing authority." *Clark v. S.C. Tax Comm'n*, 259 S.C. 161, 169, 191 S.E.2d 23, 26 (1972) (internal quotation marks omitted).

The definition of "agricultural packaging" is found in § 12-6-3360, which provides a jobs tax credit for manufacturers and agricultural packagers meeting certain requirements. Section 12-6-3360(M)(16) defines "agricultural packaging" as

> the technology of enclosing or protecting or preserving agricultural products for distribution, storage, sale, and use. Packaging also refers to the process of design, evaluation, and production of packages used for agricultural products. Packaging can be described as a *coordinated system of preparing agricultural goods for transport, warehousing, logistics, sale, and end use*." (emphasis added).

Here the statute clearly envisions a more expansive concept of "agricultural packaging," to include the transportation and warehousing both before and after the literal packaging. This definition includes the receipt of raw produce and placement of the produce on cooling racks, as well as the offloading labeling and control of the finished packaging to storage and ultimate delivery to customers.

The regulations defining "machine" greatly expand the definition beyond traditional notions of the term. For example, S.C. Code Ann. Regs. 117-302 provides that *patterns* for machinery parts and *chemicals* used in the manufacturing process qualify for the Machine Exemption. S.C. Code Ann. Regs. 117-302 (2013). This definition also includes *attachments* to machines. South Carolina Tax Commission, SC Technical Advice Memorandum #94-3 (Tax) (1994). Further, in Rev. Rul. 13-3, the Department found that even the component parts used to construct a manufacturing machine qualified as a "machine" for purposes of the exemption. In the oft-cited *Hercules Contractors and Engineers v. S.C. Tax Commission*, 280 S.C. 426, 313 S.E.2d. 300 (Ct. App. 1984) decision, the Court of Appeals held that vats and basins used in a wastewater treatment facility which performed no processing were exempt. "Even its railings, walkways and ladders *are required by state and federal law* and are thus necessary to the overall function of the system." *Id.*, 280 S.C. at 430, 313 S.E.2d. at 303. (Emp. added).

So while the definition of a "machine" is broad, the key becomes whether the purchases are "*integral and necessary* to the manufacturing process," such that "the product being manufactured is being manufactured 'for sale'" (emphasis added). S.C. Regs. 117-302.5 provides a three-part test to determine whether a machine is "integral and necessary" to the manufacturing process:

> (1) The machine is used at a manufacturing facility. . . . It does not apply to machines used at a facility whose purpose is retailing, wholesaling, distributing, or some other non-manufacturing purposes.
> (2) The machine is used in, and serves as an essential and indispensable component part of the manufacturing process, and is used on an ongoing and continuous basis during the manufacturing process. A machine is not part of the manufacturing process merely because it is integral and necessary to the manufacturer.
> (3) The machine must be substantially "used in manufacturing . . . tangible personal property for sale." The statute does not required that the machine be used exclusively for manufacturing; however, incidental manufacturing use will not qualify for the exemption. For purposes of

> the exemption, more than one-third of a machine's use in manufacturing is substantial.

S.C. Regs. § 117.302.5(B)(1). Importantly, the machine exemption applies so long as 1/3 of the machine's use is devoted to manufacturing purposes. S.C. Regs. Section 117-302.5 provides that in order to be exempt, the machine must be "*substantially* 'used in manufacturing ... tangible personal property for sale'" (emphasis added). According to that regulation, "[t]he statute does not require that the machine be used exclusively in manufacturing; however, incidental manufacturing use will not qualify for the exemption. For purposes of the exemption, *more than one-third of a machine's use in manufacturing is substantial.*" Section 117-302.5(B)(1)(c). (Emp. added). This means that a piece of machinery like a forklift can serve many purposes within a manufacturing facility and still be eligible for the exemption, so long as the taxpayer can establish that more than 1/3 of its use is for manufacturing.

Generally, states follow one of two distinct lines of authority when determining what qualifies as machinery used in manufacturing: (1) the Integrated Plant Concept or (2) the "Ohio Rule". *See generally* Hellerstein, State Taxation, at § 14.05. The more restrictive Ohio Rule defines "manufacturing" as "essentially a transformation or conversion of material or things into a different state or form from that in which they originally existed." *Nat'l Tube Co. v. Glander*, 105 N.E.2d 648, 650 (Ohio 1952). Only those assets which physically transform raw materials during the manufacturing process into a different form are eligible for the exemption. In other words, "the test is not whether the property is essential to the operation of the plant but whether it is an actual part of the process of manufacture." *Hawes v. Custom Canners, Inc.*, 173 S.E.2d 40 (Ga. Ct. App. 1970).

On the other hand, the Integrated Plant Concept is less restrictive. As the name implies, machinery shall be eligible for the exemption if it performs an essential or indispensable function

in the taxpayer's manufacturing operations, regardless of whether it actually causes a physical change. This test is derived from *Niagara Mohawk Power Corp. v. Wanamaker*, 286 A.D. 446 (N.Y. 1955). In finding that now material handling equipment including both coal handling and ash disposal equipment fell within the exemption (including the cranes and car dumper that unloaded incoming coal; conveyor belts that moved the coal to the boiler; crushers and sprayers that processed the coal; and slag lines that carried ash from the boiler), the *Niagara* court determined the relevant questions to be:

> (1) Is the disputed item necessary to production?
> (2) How close, physically and causally, is the disputed item to the finished product?
> (3) Does the disputed item operate harmoniously with the admittedly exempt machinery to make an integrated and synchronized system?

The court found that the crane and car dumper were as essential to production as the generator itself, since a serious breakdown in operation would quickly stop or impair the output of electricity. The court also noted that while some structures may not play as active a role as other parts, "activity is not the test of directness." Instead, "[t]he important thing is that all parts of the plant contribute, continuously and vitally, to production, and they are all integrated and harmonized."

In *Spring Industries, Inc. v. Department of Revenue*, 99-ALJ-17-0153-CC (1999) Chief Administrative Law Judge Kittrell acknowledged that Professor Walter Hellerstein, author of the above-cited treatise on state taxation, testified that South Carolina is classified as an "integrated plant theory state." In an unpublished opinion, the court of appeals affirmed the finding. It noted that although the Department urged the court to "interpret the term 'machines used in manufacturing' to include only items that are part of a production line," this position was "inconsistent with the result in *Hercules Contractors and Engineers, Inc. v. South Carolina Tax Commission*, 280 S.C. 426, 313 S.E.2d 300 (1984)] and the language in [§ 12-36-2120(17)] that

only requires a machine to be 'used in manufacturing,' rather than 'used directly in manufacturing,' as the [Department] suggests." *S.C. Dep't of Rev. v. Springs Indus., Inc.*, 2003-UP-029 (Ct. App. 2003). Thus, South Carolina law provides that so long as the equipment in question performs an essential function in the taxpayer's manufacturing operations, it will qualify for the machine exemption to the sales tax. To reiterate: In *Hercules*, even purchases of ladders, walkways, and scaffolding were found to be exempt from sales tax under this machine exemption.

The DOR audit held that the machinery and equipment used to move the fresh produce into the manufacturing process were not exempt. There is no dispute that the machinery used in the cutting and processing was exempt.

In this case, given Petitioner's highly regulated business as a fresh food processor, the tools and equipment used immediately before and after the actual processing of the fresh produce is integral to the overall processing/manufacturing process, as well as the health and safety functions. Without the process that occurs in these climate-controlled areas, it would seriously impair the ability of the taxpayer to efficiently and safely prepare a finished product for sale and distribution. The refrigeration itself, as well as the tools and equipment used therein, contributes, both "continuously and vitally, to production" and the assembly line production is surely "integrated and harmonized," as described in the Integrated Plant concept above.

Moreover, federal guidelines mandate all aspects of the refrigeration. According to Section VIII, Part C, Item 3, of the Food and Drug Administration's Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables, fresh–cut produce is recommended to be stored in areas with a temperature of less than or equal to 41 degrees Fahrenheit. The Food Safety Modernization Act of 2011, Section 117.93, provides even further and mandates that any "Storage and transportation of food must be under conditions that will protect against allergen cross-contact

and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container." Additionally, 21 C.F.R. § 110.80(b) provides:

> (b) Manufacturing operations. (1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.
>
> (2) *All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms*, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, aw, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.
>
> (3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:
>
> > (i) Maintaining refrigerated foods at 45 deg. F (7.2 deg. C) or below as appropriate for the particular food involved. (Emp added.).

Since keeping the temperature of this product at or below 41 degrees must be done to prevent contamination of our product, and must be stored (by Congressional Act) in certain areas of plant to prevent cross-contamination (storage racks are the only viable option) then it is considered continuous, on-going and integral to the manufacturing process and therefore exempt. Even once the product is loaded onto Petitioner's trucks, the 41-degree requirement must be met until it is ready to be sold inside a restaurant. Temperature recorders are required for refrigerated

trucks to ensure that the product never went above this requirement at any time while in transit. In addition to federal law, customer contractual requirements are equally as stringent.

Based on the foregoing, the Department improperly limited the exemption to only those items used in the cutting process. The highly specialized and highly-regulated nature of the food processing industry mandates a more expansive view of the manufacturing process to include activities both before and after the literal processing of the produce. Purchases of these items are exempt from tax under the Machine Exemption (§ 12-36-2120(17)) using the integrated plant theory, which has been adopted by the South Carolina Court of Appeals.

2. Specifically, protective clothing related to maintaining the physical environment of the processing areas also are Exempt under the Machine Exemption

At first blush, protective clothing does not seem to fit the definition of machinery and equipment (any more than the ladders, walkways, and scaffolding in the *Hercules* case). The Department itself acknowledges, however, that protective clothing fits within the machinery and equipment ambit. The Department's published guidance provides that "[p]rotective clothing worn by an employee working in the area in which the manufacturing process occurs does not qualify as a machine and is not exempt from the tax as a machine used in manufacturing tangible personal property for sale under Section 12-36-2120(17)." However, that guidance is intended to apply to protect the worker's own clothing from dirt, paint, oils, etc. which are given off in the manufacturing process. On the other hand, the clothing worn by Petitioner's workers serves a substantively different purpose. Petitioner's gear protects *the produce* from the worker (for the purpose of protecting the ultimate consumer). The gear puts a barrier between the end product – the chopped vegetable – and the workers entering the high care area. The gear is absolutely vital and is required by state and federal law as detailed below to maintain the physical environment

necessary to produce Petitioner's finished product in a safe and unadulterated manner. The Court of Appeals in *Hercules* held that railways, walkways and ladders were exempt under the machine exemption as they were required by state and federal law and thus were necessary, to the overall function of the system. The same applies to Petitioner's protective clothing. The gear creates a physical barrier that maintains the integrity and purity of Petitioner's manufacturing process, is required by state and federal law and thus as described above, must be considered an integral part of that process.

3. The remaining purchases at issue are exempt from tax under the Machine Exemption

The Court finds the following machinery and equipment exempt under the machine exemption as all (1) are used in a manufacturing facility; (2) serve as an essential and indispensable component part of the manufacturing process on an ongoing and continuous basis; and (3) are substantially used (more than one-thirds use) in manufacturing tangible personal property for sale. The Bar Code scanner is required by federal law to track produce, and the mobile computer stands assist in the gathering and analysis of that tracking information. The Forklifts and batteries were substantially used to move 800-1,600 pounds of raw produce into the first step of the manufacturing process – onto the conveyor belt. Mr. McEntire testified that up to 12 of the 30 Forklifts on site are used to feed the manufacturing process. Because these Forklifts are used interchangeably at the site, and because more than 1/3 of the forklifts are required to feed the manufacturing process (which runs nearly continuously), it is reasonable to conclude that each is used at least 1/3 of the time for manufacturing purposes. Therefore, all of the Forklifts are eligible for the exemption. Racks were specifically designed to maintain the temperature of produce at federally mandated levels. Pallet flow breaks performed a significant safety function while moving produce. Water tanks distribute water in the middle of the production process. Generators

were used to ripen tomatoes. Hand trucks were used to move produce in the middle of the production process. Black ink was used to mark the finished products. Petitioner's stainless steel floor drain covers filtered wash water during the water recycling process. The specialized plastic shelves were used to shelve produce in the control sample room. Petitioner's witnesses testified that floor treatment chemicals and cleaning machines were used daily in the manufacturing area. The stacking containers hold the component pieces that compose the finished product of mixed produce, and thus are an indispensable part of the process. Blower fans circulate the chilled air in the facility. Without the blower fans, Petitioner would be unable to maintain the constant temperature required for its manufacturing operations. Finally, maintenance tools and the utility cart holding the tools are used primarily on the exempt machines.

Petitioner's witnesses all testified that the above machinery and equipment were used directly in the manufacturing process and each served an essential and indispensable role. The Department provided no contrary testimony.

B. Protective Clothing for Class 100 Facility (12-26-2120(54))

The Proposed Assessment also assessed use tax on protective clothing related to maintaining the physical environment of the processing areas. Petitioner makes substantial purchases of such items on an annual basis. The DOR denied the exemption based upon the Department Determination and the testimony at trial for two reasons: (1) the Petitioner has not established that it met the Class 100 Clean Room requirements; and (2) that protective clothing was required to work in the Clean Room. Petitioner established at trial that the high care area met the Class 100 Clean Room environment and that the protective clothing at issue was required to work in such area. The Department provided no contrary testimony. Accordingly, purchases of protective clothing are also exempt from tax based on the Class 100 facility exemption discussed

below.

S.C. Code Ann. § 12-36-2120(54) exempts from sales tax "clothing and other attire required for working in a Class 100 or better as defined in Federal Standard 209E clean room *environment*." (emphasis added.) Note that the exemption specifically includes the term "environment". In other words, the exemption does not expressly track the Federal Standard 209E, which uses the term "cleanroom." Therefore, the intent of the statute is to provide a more expansive exemption for environments which have qualities of the Federal Standard 209E. The parties agreed that Federal Standard 209E was cancelled in 2001 (see Notice of Cancellation filed by U.S. General Services Administration (GSA), and ISO 14644-1 was adopted in its place.

"Class 100" describes the number and size of particles permitted per volume of air in "cleanroom" environments. Class 100 under Federal Standard 209E, which is equivalent to ISO 5, permits 100 particles of 0.5 microns or greater per cubic foot.

Although the FDA does not appear to have a micron filtration requirement *per se*, it does require all food processors to establish a written Hazard Analysis Critical Control Point (HACCP) Plan under 21 C.F.R. § 117.130(a)(2) that establishes good manufacturing practices. If a manufacturer does not have a HACCP Plan, then it can be found in violation of Part 117 of the FDA regulations and can be censured, fined, or shut down by the FDA. In all of its published guidance, the FDA recommends filtering both air within a facility and compressed air that comes into contact with produce to at least 0.3 microns in order to remove bacteria and molds. Thus, a fresh food producer like the Petitioner meets the Class 100 standard when it satisfies the FDA filtration level.

ISO industry specialists reference providers of clothing and other supplies which are

required to ensure ISO integrity and compliance. According to Jan Eudy[1] of Controlled Environments Magazine, the following chart is illustrative of the garment configurations for each ISO class of air cleanliness.

Garment system configurations for different classes of air cleanliness.

Apparel Type	Air Cleanliness Classes of ISO 14644-1:1999[1]							
	ISO Class 8	ISO Class 7	ISO Class 6	ISO Class 5	ISO Class 5 Aseptic	ISO Class 4	ISO Class 3	ISO Class 1, ISO Class 2
Inner Suit	AS	AS	AS	R	AS	R	R	R
Hair Cover (Bouffant)	R	R	R	R	R	R	R	AS
Woven Gloves	AS	AS	AS	AS	NR	NR	NR	NR
Barrier Gloves	AS	AS	AS	AS	R	R	R	R
Facial Cover	AS	AS	AS	R	R	R	R	AS
Hood	AS	AS	AS	R	R	R	R	AS
Powered Headgear	AS	AS	AS	AS	AS	AS	AS	R
Frock	R	R	AS	AS	NR	NR	NR	NR
Coverall	AS	AS	R	R	R	R	R	R
Two-Piece Suit	AS	AS	AS	AS	NR	NR	NR	NR
Shoe Cover	R	R	AS	AS	NR	NR	NR	NR
Boot	AS	AS	R	R	R	R	R	R
Special Footwear	AS	AS	AS	AS	AS	AS	AS	AS
Suggested Frequency of Change[2]	2x/week	2x/week	3x/week	1x/day	Per Entry	Per Entry	Per Entry	Per Entry

[1] For correlation of ISO air cleanliness classes to the former FED-STD-209 classes, refer to Table 1 in this document.
[2] Consideration should be given to the effects of seasonal conditions in some geographical areas. Note that the suggestions made are not based on scientific data but instead reflect the collective experience offered by the working group. Individual requirements for change frequency should be determined on a case-by-case basis.
R = Recommended
NR = Not Recommended
AS = Application Specific

[2]

Table 1: IEST-RP-CC003 gowning configurations chart.

Under Class 5 of ISO (formerly FS209E), this chart demonstrates that there is no garment configuration which is "NR," (not required). All of the protective clothing at issue in this audit is either required (R) or application specific (AS). As stated below, federal health and safety law

[1] *See* https://www.cemag.us/article/2015/04/professional-profile-jan-eudy
[2] Jan Eudy, *Cleanroom Garment Selection*, CONTROLLED ENVIRONMENTS (Apr. 14, 2014), https://www.cemag.us/article/2014/04/cleanroom-garment-selection. *See also* BERNER INTERNATIONAL, https://www.berner-safety.de/recommended_cleanroom_clothing_per_cleanroom_classes_en_1415.html.

requires *all* of the protective clothing at issue in this audit, and is thus Application Specific. In addition, Petitioner's witnesses all testified that the Protective Clothing was required in the clean room environment and the Department provided no contrary testimony. Indeed, common sense indicates that it would serve little purpose to filtrate air if Petitioner's employees were releasing E. coli, Listeria, and Salmonella from their hands and clothing onto the produce.

Although the FDA expects air to be filtered to 0.3 microns, the taxpayer filters its ambient air to 0.3 microns and its compressed air to 0.1 microns (see Petitioner's Exhibit 9). BRC Global Standards, an industry-leading safety and quality certification program, conducted annual extensive audits of Petitioner regarding the quality, safety and operational manufacturing standards during the audit period. From its 2015 annual audit of Petitioner, BRC Global Standards concluded that the taxpayer's "[c]ompressed air used directly in contact with the product contact surfaces is filtered by a series of two filters (first filter 1 micron, second filter 0.1 micron)." This means the compressed air used by the Petitioner meets, and in fact significantly exceeds, the "Class 100 or better" described by the exemption, which requires 0.5 microns. The taxpayer's fresh-cut produce is in a Class 100 environment, and all the protective clothing at issue is required in such environment. Accordingly, all protective clothing used in that environment is exempt under § 12-36-2120(54). Taxpayer cannot achieve the required airborne particulate requirement cleanliness as required by ISO 14644-1 (formerly FS209E) without the use of protective safety attire as discussed herein. For the above mentioned reasons, Taxpayer's processing area meets the definition of a "Class 100 or better" clean room as required under S.C. Code Ann. § 12-36-2120(54). Taxpayer is entitled to a sales tax emption on the clothing and other supplies used in conjunction with its clean room.

While a Department Determination is deemed correct, the auditor was not aware the

Petitioner's facility had been certified as a Class 100 Clean Room and she was not aware that protective clothing is required to maintain the Class 100 environment. In addition, she was under the impression that the entire facility had to meet the Class 100 requirement, and not just the high care area where the protective clothing was used. Lastly, the auditor was not aware that the FDA recommends a Class 100 Clean Room environment at a fresh foods processing facility. This was the auditor's first audit of a Class 100 Clean Room.

C. Pollution Control Exemption (§ 12-36-2120(17))

Finally, to the extent the protective clothing is not exempt under either the machine exemption or the Class 100 exemption described above, the purchases deemed taxable in the Proposed Assessment are exempt under the Pollution Control Exemption provided in § 12-36-2120(17), which exempts machines "necessary to comply with the order of an agency of the United States or of this State for the *prevention or abatement of pollution* of air, water, or noise that is *caused or threatened by any machine used* as provided in this section." The pollution control regulation, Regulation 117-302.6 states in relevant part that:

> Frequently, these machines [that are exempt from sales or use tax under S.C. Code § 12-36-2120(17)] cannot be operated when the same pollute beyond regulated levels and in compliance with orders of agencies of the United States or of this state to abate or prevent pollution caused or threatened by the operation of such machines it is necessary to install *other machines that are designed and operated exclusively for the purpose of abating or preventing this pollution.* The purpose of this regulation is to classify the machines, their parts or attachments, as machines used in mining, quarrying, compounding, processing or manufacturing of tangible personal property when the same are installed and operated for compliance with an order of an agency of the United States or of this state to prevent or abate pollution caused or threatened by the operation of other machines used in the mining, quarrying, compounding, processing and manufacturing of tangible personal property. (Emphasis added.)

Regulation 117-302.6 further clarifies that:

> The term "machine" as defined in Section 12-36-2120(17) shall include machines, their parts and attachments, when the same are necessary to comply with the order of an agency of the United States or of this state for the prevention or abatement of pollution that is caused or threatened by any machines used in the mining, quarrying, compounding, processing and manufacturing of tangible personal property.

Thus, the Petitioner, a manufacturer of fresh produce, is exempt from taxes on machines which are necessary to comply with the order of a state or United States agency to prevent or abate pollution that is precipitated by other manufacturing machines used in the process of cutting and bagging fresh produce. From this, the court derives three elements that must be met: (1) a machine that (2) prevents or abates pollution caused by machines used in the manufacturing process and is (3) necessary to comply with the order of an agency. "As a general rule, tax exemption statutes are strictly construed against the taxpayer." *Se.-Kusan, Inc. v. S.C. Tax Comm'n*, 276 S.C. 487, 489, 280 S.E.2d 57, 58 (1981) (citation omitted). This means that "constitutional and statutory language will not be strained or liberally construed in the taxpayer's favor," but neither will the court "search for an interpretation in the [Department's] favor where the plain and unambiguous language leaves no room for construction." *Id.* (citation omitted).

The following summarizes the applicable requirements.

1. **Purchases at issue prevent or abates pollution "caused or threatened by" machines used in the manufacturing process**

    i. **E. Coli, Salmonella, and Listeria are all "pollution."**

The major thrust of the Department Determination was that food contamination and diseases are not "pollution." While the Department Determination is presumptively correct, the DOR auditor testified that she didn't know what the definition of "pollution" was under the statute, and didn't know enough about E. coli, Listeria or Salmonella to determine whether they constituted "pollution." (This was the auditor's first audit of a fresh foods manufacturing facility.) In addition, Corey Smith, the DOR witness from the Policy Section, testified at trial that he considered such

potentially serious (if not fatal) diseases as "pollution."

Section 12-36-2120(17) does not define the word "pollution." Pollution is defined by Black's Law Dictionary as, "[t]he presence of *harmful substances* (*either physical or gaseous*), noise or energy (radiation) within a certain area, that *causes harm* to the surroundings, altering the natural environment around which it has been excreted."[3] Other dictionary definitions are similar. For example, Wikipedia defines "pollution" as "the introduction of *contaminants* into the natural environment that cause adverse change." Wikipedia, *https://en.wikipedia.org/wiki/Pollution* (emphasis added). Dictionary.com defines "pollution" as "1. the act of polluting or the state of being polluted, 2. the introduction of *harmful substances* or *products* into the environment." http://www.dictionary.com/browse/pollution (emphasis added). The DOR auditor agreed at trial with these definitions.

When determining "pollution," it is important to consider not only the harmful microbes at issue (i.e., Listeria, E. coli, salmonella), but also the host/carrier of those microbes. These microbes are typically transmitted through human and animal feces. This means the microbes are being transported when fecal matter lands on or around the produce, and then travels on the produce to the processing facility. Fecal matter can also be transported into the facility on the shoes and feet of employees, particularly those with pets or who live in rural areas with deer and other wild animals. All of Petitioner's control efforts are focused on the prevention or abatement of fecal pollution into the water or air. The Environmental Protection Agency recognizes the significant threat of fecal pollution:

> *Fecal pollution of water from a health point of view is the contamination of water with disease-causing organisms (pathogens) that may inhabit the gastrointestinal tract of mammals, but with particular attention to human fecal sources as the most relevant source of human illnesses globally.* Ingestion of water contaminated with feces is responsible for

[3] Black's Law Dictionary, https://thelawdictionary.org/pollution (emphasis added).

> a variety of diseases important to humans via what is known as the fecal-oral route of transmission. Food, air, soil, and all types of surfaces can also be important in the transmission of fecal pathogens, and thereby implicated in disease outbreaks. Most fecal microorganisms, however, are not pathogenic. Indeed, some are considered beneficial to the host as they can outcompete pathogens for space and nutrients, complement the biochemical potential of the host's gastrointestinal tract, and help in the development of the host immune system. Nonetheless, animal feces can also carry a number of important frank and opportunistic pathogens, capable of inflicting debilitating illnesses and, in some cases, death. In 1998, it was estimated that 2.2 million deaths were associated with diarrhea each year, a good percentage of them due to fecal pollution of water, with the vast majority of victims being children in poor countries (WHO, 2000). This should not be a surprise as it has been estimated that more than 1 billion people worldwide lack access to safe drinking water, and more than 2 billion lack sanitation. Sadly, very little progress has been made in the last 20 years to ameliorate these problems, particularly due to the rapidly increasing global population. *On the contrary, problems associated with fecal pollution of water are likely to worsen in coming decades*, as more people are moving to coastal areas, most people now live in urban centers, many of which have out of control growth rates, and demands for animal meat products are increasing due to current trends in dietary regimes. *Considering that per capita water availability and quantity are diminishing worldwide, it is reasonable to assume that fecal pollution of water is one of the most important and difficult challenges for future generations.* (emphasis added).[4]

Moreover, there is a large amount of case law throughout the United States which categorizes contamination of food as a pollutant with respect to a commercial insurance policy where the term "pollutant" is specifically defined in the *exclusion section* of such policies. The Court of Appeals of Wisconsin held that the term " 'contaminants' as used in [the] pollution exclusion of [a] commercial property insurance policy, included bacteria, and thus the insurance policy excluded coverage *for any losses resulting from bacterial outbreak at insured's food processing facility*." *Landshire Fast Foods of Milwaukee, Inc. v. Employers Mut. Cas. Co.*, 269 Wis.2d 775, 783, 676 N.W.2d 528, 532 (Ct. App. 2004) (emphasis added). In this case, Landshire,

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[4] Santo-Domingo, J.W. and N. Ashbolt, Fecal Pollution of Water, extract available at https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NERL&dirEntryId=196784.

a food preparer, delivered sandwiches containing listeria to its client, Great Lakes Naval Training Station commissary. *Id.* At 778, 676 N.W.2d at 529. Once the contamination was discovered, Great Lakes returned all of the contaminated food to Landshire. *Id.* Landshire determined that the food contamination occurred on a meat slicer at their facility. *Id.* At 779, 676 N.W.2d at 529. After this contaminated food incident, Landshire "submitted claims for loss of income, loss of product, sanitizing expenses, and costs related to investigating the source of the bacteria" to their insurance company. *Id.* At 779, 676 N.W.2d at 530. Landshire's insurance policy contained what is commonly referred to as a pollution exclusion. *Id.* At 782, 676 N.W.2d at 531. Landshire's insurance policy specifically stated, "[w]e will *not pay for loss or damage* caused directly or indirectly by any of the following . . . Discharge, dispersal, seepage, migration, release or escape of '**pollutants**' unless the discharge, dispersal, seepage, migration, release or escape is itself caused by . . . .". *Id* (emphasis added). Furthermore, the policy defined pollutants as " 'any solid, liquid, gaseous or thermal irritant or **contaminant**, including smoke, vapor, soot, fumes, acids, alkalis, chemicals and waste." *Id* (emphasis added). The parties in this case disputed the actual scope of the term "contaminant," and specifically whether listeria was a "contaminant." *Id.* at 782-83, 676 N.W.2d at 531. To answer this question, the court looked to *Richland Valley Products, Inc. v. St. Paul Fire & Cas. Co.*, which held that:

> [C]ontamination 'connotes a condition of impurity resulting from mixture or contact with a foreign substance,' that that it means 'to make inferior or impure by mixture; and impairment of impurity; loss of purity resulting from mixture or contact,' a definition the court found consistent with common understand and WEBSTERS NEW INTERNATIONAL DICTIONARY. . . .

201 Wis.2d 161,169-70, 548 N.W.2d 127, 169 (Ct. App. 1996) (quoting *American Casualty Co. of Reading, P.A. v. Myrick*, 304 F.2d 179, 183 (5th Cir. 1962)) (emphasis in original). The court ultimately held that the term "contaminant" in an insurance contract such as the one in dispute in

the case is not susceptible to multiple interpretations. *Landshire,* 269 Wis.2d at 785, 676 N.W.2d at 533. Therefore, the food contamination caused by listeria was a *pollutant* and was thus excludable from an insurance claim by Landshire. *Id.*

South Carolina case law is nearly identical to the states discussed above. For example, in *Helena Chemical Co. v. Allianz Underwriters Ins. Co.*, the Supreme Court of South Carolina held that the pollution exclusion in the plaintiff's policy barred its claims. 357 S.C. 631, 641, 594 S.E.2d 455, 460 (2004). In *Helena*, the Court noted that almost all insurance policies contain an identical pollution exclusion policy. *Id.* The Court went on to state that "pollution arising from ordinary business operations is not covered. *But* if the damage were caused by a 'sudden and accidental' discharge, release, or escape of pollutants, *then the insurers must provide coverage*." *Id* (emphasis added). Because the Court held that "the *contamination* at the various sites was caused by Helena's routine business operations and was, therefore, not unexpected and accidental," plaintiff fell under the pollution exclusion. *Id.* at 642, 594 S.E.2d at 460.

Here, with Taxpayer's case, even though S.C. Code Ann. § 12-36-2120 *does not* contain a definition of "pollutant," insurance policies throughout the entire country repeatedly and continuously consider contaminants such as bacteria on foods to be a "pollutant" due to its "contaminating" nature. *See also Nova Cas. Co. v. Waserstein*, 424 F.Supp 1325, 1334 (S. D. Fla. 2006) (holding that "living organisms," "microbial populations," "airborne and microbial contaminants," and "indoor allergens" are contaminants and are excluded from coverage under the insurance policies pollution exclusion). Based upon the foregoing, I conclude that E. coli, Listeria, and Salmonella constitute "pollution." In addition, the use of Petitioner's safety attire protects against pollution through the contamination of food.

Taxpayer's primary reason for using such safety attire is to prevent an outbreak of a foodborne illness. An example of the type of outbreak for which Taxpayer is trying to prevent can be illustrated by a recent multi-state outbreak of Listeriosis in packaged salads manufactured by Dole at a processing facility in Springfield, Ohio[5] (The Taxpayer in this matter packages salads). In this Springfield, Ohio outbreak, "[e]pidemiologic and laboratory evidence indicated that packaged salads produced at the Dole processing facility in Springfield, Ohio. . .were the likely source of this outbreak."[6] According to the FDA, "[their] inspection report. . .showed that Dole's tests of surfaces at the plant came back *positive* for Listeria on *nine* separate occasions in 2014 and 2015."[7] This outbreak of Listeria led to the hospitalization of twelve individuals, as well as one *death.*[8] In another instance, "a family-owned farm in Colorado [Jensen Farms] became the focal point of the largest foodborne illness outbreak in the US in 25 years."[9] This outbreak, which was caused by Listeria in cantaloupe, "sickened 146 people in 28 states, killed 30 and caused one pregnant woman to miscarry, according to the Centers for Disease Control and Prevention (CDC)."[10] The Food and Drug Administration determined that this *entire* outbreak could have been prevented if "Jensen Farms had *maintained its facilities in accordance with existing [then] voluntary FDA guidance.*"[11] (FDA rules are no longer voluntary.) Outbreaks of foodborne illness are extremely deadly to individuals of all ages. Preventing pollution from leaching onto/attaching to the food product at Taxpayer's facility is of the utmost importance.

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[5] Centers for Disease Control & Prevention, https://www.cdc.gov/listeria/outbreaks/bagged-salads-01-16/index.html.
[6] *Id.*
[7] NBC News, https://www.nbcnews.com/business/business-news/dole-under-federal-investigation-after-deadly-listeria-outbreak-n565196 (emphasis added).
[8] Reuters, https://www.reuters.com/article/us-usa-listeria-dole/listeria-contaminated-salad-from-dole-food-kills-one-cdc-idUSKCN0V02CE (emphasis added).
[9] Chris Wiant, *The Jensen Farms Cantaloupe Outbreak: How to Avoid Repeating A Tragedy*, Water Quality & Health Council (Jan. 20, 2012), https://waterandhealth.org/disinfect/food_safety/jensen-farms-cantaloupe-outbreak-avoid-repeating-tragedy/.
[10] *Id.*
[11] *Id* (emphasis added). Furthermore, note that this FDA Guidance is no longer voluntary, *see* 21 C.F.R. § 117.

In the food processing industry, there are three primary foodborne illnesses which cause a majority of sickness and death to consumers: 1. Listeria Monocytogenes, 2. E. coli O157:H7, and 3. Salmonella. According to the CDC, "[l]isteriosis is a serious infection caused by the germ *Listeria Monocytogenes.*"[12] The CDC has a webpage specifically dedicated to "Selected Multistate Outbreaks" where the CDC was the lead public health agency.[13] In Taxpayer's industry, E. coli O157:H7 is most commonly transmitted via the transfer of feces.[14] In addition to required hand washing and cleanliness, safety attire such as gloves and shoe/foot covers severely minimize the transfer of such a pollutant from employees to Taxpayer's produce. Lastly, with respect to Salmonella, such dangers of contamination are similar to E. coli O157:H7 (transfer of human or animal feces). The safety attire purchased and used by Taxpayer prevents the pollution of produce at is facility and is a primary reason for Taxpayer's strong food safety record.

Since Taxpayer has demonstrated that the safety attire protects against "pollution," it must also establish that the pollution for which it protects against consists of air, water, or noise. According to the World Health Organization:

> Foodborne illnesses are usually infectious or toxic in nature and caused by bacteria, viruses, parasites or chemical substances entering the body through *contaminated food* or water.
>
> *Foodborne pathogens* can cause severe diarrhoea [sic] or debilitating infections including meningitis.
>
> Chemical contamination can lead to acute poisoning or long-term diseases, such as cancer. Foodborne diseases may lead to long-lasting disability and death. Examples of unsafe food include uncooked foods of animal origin, *fruits and vegetables* contaminated with faeces [sic], and raw shellfish containing marine biotoxins.[15]

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[12] Centers for Disease Control and Prevention, https://www.cdc.gov/listeria/faq.html (emphasis in original).
[13] *See* Centers for Disease Control and Prevention, https://www.cdc.gov/listeria/outbreaks/index.html.
[14] *See also* Foodsafety.gov, *https://www.foodsafety.gov/poisoning/causes/bacteriaviruses/ecoli/index.html.*
[15] World Health Organization, Food Safety-Key Facts (2017), http://www.who.int/news-room/fact-sheets/detail/food-safety (emphasis added).

Such contaminated food, if not disposed of properly, can contaminate the water supply. Taxpayer is the manufacturer in a very large and diverse supply chain. Once product leaves Taxpayer's facility, within a short period of time, due to the spoilage nature of produce, it is disseminated to thousands of businesses throughout the Southeast. If Taxpayer did not prevent the pollution as described above, the ultimate and immediate affects to the water supply of communities throughout the Southeastern United States could be substantial if such pathogen contaminated food is not disposed of properly.

Furthermore, Taxpayer uses three-hundred thousand (300,000) gallons of water per day at its facility, and discharges at least 150,000 gallons into the municipal sewer system daily. Water is the means by which the Petitioner is able to deliver its sanitizing agents to the produce and the facility. Approximately half of that water is recycled, and the other half of the water makes its way through the local sewage system. Taxpayer's use of safety materials directly prevents pollution which could contaminate the water supply at Taxpayer's facility and subsequently enter the counties water supply and/or rivers. After a recent Listeria outbreak in Arizona, the Food and Drug Administration determined that that the root cause was water found in a nearby stream.[16] After an extensive investigation, the Food and Drug Administration concluded that:

> [t]hree samples of irrigation canal water collected by the team were found to contain Ecoli O157:H7 with the same rare molecular fingerprint (using whole genome sequencing (WGS)) as the strain that produced human illnesses (the outbreak strain). These samples were collected from an approximate 3.5-mile stretch of an irrigation

[16] See Cynthia Hubert, *Heading to the American River this Week? Here's where E. Coli Levels are High*, Sacramento Bee, available at https://www.sacbee.com/news/article214295669.html; Sandee LaMotte, *Deadly E. Coli Outbreak in Lettuce Traced to Contaminated Water*, available at https://www.cnn.com/2018/06/29/health/e-coli-romaine-lettuce-outbreak-cause/index.html; AP, *Source of Romaine Lettuce E. Coli Outbreak Identified,* https://www.cbsnews.com/news/source-of-romaine-lettuce-e-coli-outbreak-identified/; Maggie Fox, *Dirty Canal Water May Have Tainted Romaine Lettuce with E. Coli*, available at https://www.nbcnews.com/health/health-news/dirty-canal-water-may-have-tainted-romaine-lettuce-e-coli-n887606; Julia Jacobs, *Officials Identify a Source in the Romaine Lettuce E. Coli Outbreak*, available at https://www.nytimes.com/2018/07/01/us/romaine-lettuce-e-coli-nyt.html.

> canal in the Wellton area of Yuma County that delivers water to several of the farms identified in the traceback investigation as shipping romaine lettuce that was potentially contaminated with the outbreak strain. *This recent news story demonstrates the threat of* ***pollution*** *to area waterways is a significant issue that affects the entire community.* [17]

ii. The pollution described above is "caused or threatened by any machine" used in Petitioner's manufacturing process.

Petitioner's witnesses went into great detail to describe the manufacturing process. In short, when the fresh produce is picked and enters the trucks for transport, it may have one of the contaminants described above either inside or on the surface of the produce. When the produce is cut during the manufacturing process, either by hand or with its mechanized choppers, those contaminants can be released into the air or water, and can essentially transfer to an exposed surface, where it can subsequently contaminate other produce as well as reproduce. (This is described by the FDA as cross-contamination). Additionally, when those pollutants are exposed during the cutting process, Petitioner's water sprayers and flume systems can cause the pollutants to aerosolize – that is, be transferred into tiny droplets of water that are dispersed into the air. The spread of the pollutants also occurs when the produce is dried – both the blowers and the produce dryers (think large salad-spinners) cause potentially polluted water to aerosolize. Use of the uniforms, cleaning chemicals, and other precautions during the manufacturing process helps to ensure that the pollution, which is exacerbated and disturbed from its state while on the produce, does not spread, generally referred to as cross-contamination or cross-contact.

Of interest is SC DOR PLR # 95-8. The taxpayer was an environmental consulting firm that contracted with manufacturing companies to remediate contaminated soil and water beneath

[17] See October 24, 2018 Memorandum to the File on the Environmental Assessment; Yuma 2018 E. coli O157:H7 Outbreak Associated with Romaine Lettuce, available at https://www.fda.gov/ucm/ groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm624633.pdf.

and surrounding the manufacturer's facilities. The contaminated areas were a direct result of chemical releases from machines used in manufacturing tangible personal property for sale. The taxpayer designed and installed dual vacuum extraction systems to contain and recover contaminants from soil and ground water. The systems were constructed from pumps, tanks, piping, and vacuum extraction devices to remove water and vapor from the ground. By removing the water and vapor, contaminants were removed from the ground so they could be disposed of properly. In addition, the now-clean water could, if needed, be used as a coolant in the manufacturing plant. The taxpayer made all purchases of the component parts that were used to construct these systems.

The PLR held that such purchases fell under the pollution control exemption, stating:

> The [pollution control exemption] regulation does not restrict the exemption to machines that prevent pollution or that reduce the amount of pollution released into the environment. *The clear language of the regulation also allows the exemption for machines used to reduce the amount of pollution already in the environment.* In other words, machines used to "clean up" pollution "caused . . . by the operation of other machines that are used in the mining, quarrying, compounding, processing, or manufacturing of tangible personal property" for sale qualify for the exemption under Code Section 12-36-2120(17). (Emp. added).

iii. The purchases at issue "prevent or abate" the pollution caused by the cutters, sprayers, blowers and other machinery.

The protective clothing at issue is vital to Petitioner's the control and containment of the pollutants described above. Most importantly, the protective clothing serves as a barrier between the high care area – where those pollutants are exposed and dispersed in the air and water – and the outside. Witnesses for Petitioner testified as to the rigorous processes for entering and exiting the high care area. All are designed to ensure that none of the dangerous microbes leave that area. Without the control, Petitioner could spread those microbes outside the facility. By requiring full

dress-down when exiting the clean room, Petitioner is able to contain the pollutants that may have been released from the produce during the manufacturing process.

The protective clothing serves the additional purpose of ensuring those pollutants are not introduced into the clean room environment by Petitioner's employees. Petitioner's manufacturing process results in significant spray-back, as cutters chop the produce, sprayers and wash flumes wash down the produce, and blowers and spinners dry the produce. Through this process, a significant amount of water becomes airborne. Pollutants brought into the room from an unsanitary employee could be released into the air or introduced to water used in Petitioner's manufacturing process.

2. Necessary to Comply with the Order of an Agency

In this case, the purchases at issue are required by the both federal and state regulation and statutes. Prior case law of this Court (which was not challenged by the Department) has established that federal agency regulations satisfy this requirement. *See Duke Energy Corp. v. Department of Revenue*, Docket No. 12-ALJ-17-0031-CC (filed April 28, 2017) (exemption applied to purchase of canister system used to comply with regulations of the U.S. Nuclear Regulatory Commission, an "independent United States agency").

The FDA has established extensive regulations to combat "environmental pathogens," which are those pathogens

> capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen.
>
> Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes and Salmonella spp.* but do not include the spores of pathogenic sporeforming bacteria.

21 CFR § 117.3 (emphasis added). The following summarizes the state and federal agency guidelines requiring the use of the gear at issue.

i. FDA GMP Regulations

Specifically, 21 C.F.R. § 110.10 requires plant management to take all reasonable measures and precautions regarding the maintenance of a clean facility, including the following:

> (b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials **shall** conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:
>
> > (1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces…
> > (3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
> > …
> > (5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.
> > (6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

Furthermore, 21 C.F.R. § 117.10(b), describes the measures and precautions that firms such as Taxpayer must exercise in order to:

> conform to hygienic practices while on duty to the *extent necessary* to protect *against* allergen cross-contact and against *contamination of food.* The methods for maintaining cleanliness include: (1) *[w]earing outer garments* suitable to the operation in a manner that protects against allergen cross contact and against the *contamination* of food, food contact surfaces, or food-packaged materials. . . (5) [m]aintaining *gloves*, if they are used in *food handling*, in an intact, clean and sanitary condition, (6) [w]earing, where appropriate, in an effective manner, *hair nets, headbands, caps, beard covers,* or other effective hair restraints. . . (9) [t]aking any other necessary precautions to protect against allergen

> cross-contact and against contamination of food, food contact surfaces, or food-packaging materials with microorganisms or foreign substances. . . ."

(emphasis added). Additionally, 21 C.F.R. § 117.80(a)(1) states that:

> [a]ll operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles. (2) [a]ppropriate quality control operations must be employed to ensure that food is *suitable* for human consumption and that food-packaging materials are safe and suitable. . . (c)(2) [a]ll food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to *minimize* the potential for the growth of *microorganisms, allergen cross-contact, contamination of food,* and deterioration of food. . . (5) [w]ork-in-process and rework *must be handled* in a manner that protects against allergen cross-contact, *contamination, and growth of undesirable microorganisms*. . . (10) [s]teps such as washing, peeling, trimming, cutting, sorting, inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed *so as to protect* against allergen *cross-contact* and *against contamination.* Food must be protected from contaminants that may drip, drain, or be drawn into the food.

Finally, according to 21 C.F.R. § 117.37:

> Each plant must be equipped with adequate sanitary facilities and accommodations including:
>
> (a) Water supply. The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(emphasis added). Based on the foregoing, federal law explicitly requires all clothing at issue in this case.

ii. DHEC Statutes and Regulations

According to S.C. Code Ann. § 39-25-180(H) 39-25-180 (H)

> Good manufacturing practice regulations and their amendments now or hereafter adopted pursuant to the authority of the federal Food, Drug, and Cosmetic Act are the good manufacturing regulations of this State. However, the commissioner may adopt a regulation that prescribes conditions under which good manufacturing processes may be used in this State whether or not in accordance with regulations promulgated pursuant to the federal act.

DHEC has accordingly adopted the Part 110 and Part 117 guidelines stated above which require protective clothing.

Moreover, DHEC also has promulgated Regulation 61-25, which also provides rules and regulations for entities engaged in food production. Produce manufacturers like Petitioner comply with such regulations.

These regulations require the use of gloves, hair nets, and other protective clothing to reduce or eliminate opportunities for cross-contamination, and place responsibility for use on food protection managers. *See* S.C. Regs. 61-25, 2-103.11 (person in charge "shall ensure that … (L) employees are preventing cross-contamination of ready-to-eat food with bare hands by properly using suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment"). Section 3-301.11(B) prohibits food employees from contacting exposed, ready-to-eat food with bare hands, and requires use of gloves. Under 2-402.11(B) food employees must wear hair restraints, including hats, hair covering and nets, beard restraints, and clothing that covers body hair. Those restraints must be both designed and worn to effectively keep hair from contacting exposed food, clean equipment, utensils, and linens. *Id.* Accordingly, state law requires all the clothing at issue in this matter.

3. Is Protective Clothing a "machine?"

The Department also alluded to the issue of whether protective clothing were "machines." "The term 'machine' includes every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result." *Hercules Contractors &*

Engineers, Inc. v. S.C. Tax Comm'n, 28 S.C. 426, 431, 313 S.E.2d 300, 303 (Ct. App, 1984); *see also* S.C. Code Ann. Reg. 117-302.5(B)(1) (2012) (construing "machine" in the context of Clause A of the above subsection). A machine does not need moving parts to qualify for the exemption. *Id.* (citation omitted). While there is no DOR Policy Document on whether protective clothing constitutes a machine for the pollution control exemption, there are several policy documents which provide expansive definitions of "machines."

In S.C. Tax Commission Decision 92-19, the former Tax Commission held that stack liners and ash pond pipes and pumps were exempt as they operated exclusively in the abatement of pollution caused by the production of electricity. In S.C. Rev. Rul. # 89-7, the DOR opined that a settling basin for a wastewater treatment facility was exempt as one part of a single entity used to abate pollution and therefore purchases of materials such as concrete and steel to build the facility where likewise exempt.

At issue in PLR # 90-3 was whether concrete, reinforced steel bars and a metallic pool liner were exempt under the pollution control exemption when used to construct a gamma irradiator vault. The vault was designed and licensed for the purpose of containing gamma radiation. The vault had six foot thick walls with a specialized design to trap radiation. The vault was designed to withstand a direct airplane hit and catastrophic earthquake. The vault itself served no purpose other than to trap radiation, and it performed no processing. The ruling held under such facts that the concrete, steel, and liner used to construct the vault were exempt.

In S.C. Tax Commission Decision 89-82, the taxpayer provided radioactive waste management services consisting of processing, transporting and disposing of nuclear waste generated by nuclear power plants. At issue was the sales taxation of liners. The liners served three functions: (1) they were first transported to the power plant site where radioactive waste was

place inside them; (2) the liners then processed the waste into a more stable form, thus reducing the likelihood of nuclear accidents; and (3) the liners were then transported to disposal sites where they became permanent storage containers for holding waste. The Tax Commission staff held the liners were subject to sales taxes.

The Tax Commission disagreed, first holding that electricity is considered tangible personal property for sales tax purposes and thus the machine and pollution control exemption are applicable to nuclear generators. The Commission then found that the liners were exempt notwithstanding their storage function stating:

> In reaching this decision, we first note that the liners are machines. The term 'machine' has been defined to include 'every mechanical device or combination of mechanical power and devices to perform some function and produce a certain effect or result.' *Hercules Con. & Engineers v. South Carolina Tax Com'n.*, 280 S.C. 426, 313 S.E. 2d 300 (S.C. App. 1984). The evidence presented showed that the liners were more than mere storage tanks. They contained internal devices that processed radioactive waste into a less volatile state. This falls squarely within the definition of a 'machine.' The fact that the liners were subsequently used for storage does not detract from their function as machines. As noted in *Hercules* at page 308, a machine may have an alternate use but it still remains a machine.
>
> There is also adequate evidence indicating the liners abated pollution. Such evidence demonstrated that the processing undergone in the liners was a necessary step in the treatment of radioactive waste produced by power plants. In point of fact, nuclear utilities would not be licensed or allowed to operate without this means of processing nuclear waste. Moreover, the testimony and documentary evidence establishing these points are sufficient to meet the certification requirements of Regulation 117-173.

Lastly, in *Duke Energy, Inc. v. Department of Revenue*, *supra*, the ALC rejected the Department's argument that storage containers which contained spent nuclear fuel were not machines.

If stackliners, ash pond pipes, concrete and steel and metallic pool liner used to construct a gamma irradiator vault, and liners used in radioactive waste management services, and storage

containers constitute "machines," then certainly Petitioner's protective clothing required by state and federal law do as well.

The uncontroverted evidence in this matter demonstrates that the protective clothing are mechanical devices that act to prevent or mitigate contamination. The contamination comes from the machines essential to the production of the fresh produce, namely the cutting machines. Therefore, the court concludes that the protective clothing are machines for purposes of the statute. Furthermore, the court concludes that the protective clothing are used because of pollution produced or potentially caused (exposed) by machines necessary and integral to the Petitioner's manufacturing process.

D. Substantial Understatement

Further, to the extent the sales tax exemptions do not apply, the Proposed Assessment includes taxes outside the statute of limitations.

Petitioner contends that tax periods October 1, 2012 through May 31, 2013 are time-barred. I agree.

Generally, the Department has three years from the date the return is filed to audit and assess sales tax. However, § 12-54-85(C)(3) allows the Department to utilize a six-year statute of limitations if there is a substantial understatement of the total tax required to be shown on the return of at least 20%.

In this case, the Department issued its Proposed Assessment on July 19, 2016, which covered the period beginning October 1, 2012 and ending September 30, 2015. Petitioner appealed the proposed assessment, and the Department issued its Department Determination on March 15, 2017. The Department Determination utilized the longer assessment period, but did not provide its legal justification for that period. The general statute of limitations would have provided for an

assessment period of June 2013-September 2015. This means there are eight months which the Department opened for audit solely pursuant to § 12-54-85(C)(3).[18]

As "the final determination within the department from which a person may request a contested case hearing before the Administrative Law Court," § 12-60-30(10), the Department Determination by statute must "explain the basis for the department's determination." § 12-60-450(D)(2). Thus, the Department should be barred from utilizing a statutory mechanism to extend the assessment period when it fails to reference the basis in the Department Determination. The Department's abandonment of that argument in its Department Determination should limit the audit period at issue to June 30, 2013-September 30, 2015.

ORDER

For the reasons above, the Court finds that Petitioners are entitled to the sales tax exemptions covered above.

IT IS THEREFORE ORDERED THAT the Determination of the Department is reversed.

AND IT IS SO ORDERED.

H. W. Funderburk, Jr.
Administrative Law Judge

_____, 2019
Columbia, South Carolina

[18] Throughout the course of the audit, Petitioner agreed to extend the statute of limitations to October 1, 2012 on a number of occasions. *See* Petitioner's Exhibit 19. Its last extension was signed March 23, 2016 and expired May 31, 2016. The Department auditor acknowledged in an email that the extension did, in fact, expire. *See* Petitioner's Exhibit 17. I find the Petitioner properly preserved this argument when its representative challenged the use of § 12-54-85(C)(3) in the same email chain. *See id.*

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

McEntire Produce, Inc. Petitioner, vs. South Carolina Department of Revenue, Respondent.	)	Docket No. 17-ALJ-17-0060-CC **CERTIFICATE OF SERVICE**

I certify that a copy of the foregoing **Petitioner's Proposed Order** was served upon counsel of record for the Respondent via electronic mail and U.S. Mail as shown below this 7th day of January 2019:

Lauren Acquaviva, Esq.
Chillico & Associates, LLC
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Elisabeth Shields
SC Department of Revenue
P.O. Box 12265
Columbia, SC 29211-9979

Melinda White

South Carolina Administrative Law Court (SC ALC)

Request for Contested Case Hearing - FORM

Mail to: 1205 Pendleton St., Suite 224, Columbia, SC 29201

Last Name:	First:	Middle:	☐ Mr. ☐ Mrs. ☐ Miss ☐ Ms.	Docket No. (To Be Completed by ALC)
McEntire Produce, Inc.				

Mailing Address:	City:	State and Zip:
P.O. Box 5817	Columbia	SC 29250

Home Number:	Work Number:	Cell Number:	*E-Mail Address:

*By providing your e-mail address, you consent to receive court orders and notices via electronic transmission

REPRESENTATION

Are you representing yourself? ☐ Yes ☒ No

Are you represented by an Attorney? ☒ Yes ☐ No

Name of Attorney: Burnet R. Maybank, III/Jim Rourke

Attorney Mailing Address:	City, State and Zip:
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CASE INFORMATION

Name of Agency that Issued the Decision: Department of Revenue
(Example – Dept. of Revenue, Dept. of Insurance, DHEC)

In order to have your case processed, **you must attach the agency decision.** Is it attached?:
☒ Yes ☐ No

If no, please explain:

Date the decision was issued: February 7, 2017

Date the decision was received: February 9, 2017

RECEIVED MAR 2017 S.C. Dept. of Rev. OGC for Litigation

Please provide a brief statement regarding why the hearing is being requested and the relief sought:

Petitioner McEntire Produce, Inc. contests the Department's Determination that its purchases of electricity, certain supplies, and safety attire are subject to sales and use tax. Petitioner requests this Court determine that the purchases identified in the attached Department Determine are exempt from sales and use tax pursuant to various exemptions available under S.C. Code Ann. § 12-36-2120.

Payment via ☐ Check ☐ Money Order ☐ Cash for $ (applicable **filing fee pursuant to** ALC Rule 71) is being submitted today to the Administrative Law Court via ☐ U.S. Postal Service ☐ Hand-delivery

X _____ Your Signature or Signature of Attorney

March 7, 2017
Date

PROOF OF SERVICE (MUST BE COMPLETED)

Your Name: Jim Rourke Date: March 7, 2017 City: Columbia State: SC

I hereby certify that on the date and place listed above, I served a copy of the foregoing Request for Contested Case Hearing **on all other parties** to this matter by depositing the same in the United States Mail, postage paid, and addressed as follows (use the reverse side for any additional names):

Name and/or Agency Name	Address	City, State and Zip
South Carolina Department of Revenue	300A Outlet Pointe Blvd	Columbia, SC 29210
Lauren Acquaviva	300A Outlet Pointe Blvd.	Columbia, SC 29210

FILED
MAR 07 2017
SC ADMIN LAW COURT

X _____ Your Signature or Signature of Attorney

March 7, 2017
Date

Attention: All cases filed in the Administrative Law Court are subject to the Rules of Procedure found at the Court's website www.scalc.net or from the Clerk of Court. Failure to follow these rules may result in dismissal of your case.

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Jun 01 2020
SC Court of Appeals

THE STATE OF SOUTH CAROLINA
In The Court Of Appeals

APPEAL FROM THE ADMINISTRATIVE LAW COURT

THE HONORABLE H.W. FUNDERBURK, JR., ADMINISTRATE LAW JUDGE

CASE NO. 17-ALJ-17-0060-CC
APPELLATE CASE NO. 2019-001933

McEntire Produce, Inc., ...Respondent,

v.

South Carolina Department of Revenue, ...Appellant.

CERTIFICATE OF COUNSEL

Pursuant to Rule 210(g), SCACR, the undersigned certifies that this Record on Appeal contains all material proposed to be included by the above-referenced parties and not any other material.

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