Food Safety Plan Table of Contents

Overview

Vigon International, Inc. was founded in 1988 by Victor Fulgoni, a former Vice President of Manufacturing at Norda. The company began operation with two employees and a facility totaling 8,000 square feet.

In 1998 Vigon International was purchased by Steve Somers, formerly of Givaudan. At the time of purchase Vigon employed 10 individuals. Under the leadership of Somers, Vigon International now employs more than 105 in a facility totaling over 105,000 square feet on seventeen acres of property.

The initial growth and success of Vigon was due in large part to a unique corporate concept that Vigon developed and established within the industry: Creative Partnerships. The partnership concept has been and continues to be the foundation and guiding principle for all of Vigon's activities.

In June 2021, Vigon International was sold to Azelis Americas, LLC. The Vigon business structure and all personnel remain unchanged with Steve Somers remaining President in charge of all site activities. As part of the Purchase, Vigon International, Inc. was converted to an LLC. All subsequent references in this document have been updated to reflect the company name as **Vigon International, LLC.**

Mission Statement

Vigon International, LLC. is dedicated to creating open, honest partnerships with its customers, employees, and suppliers. These partnerships are based on utilizing the skills, talents and expertise of those involved, to benefit all. As a supplier of flavor and fragrance products, Vigon International is committed to:

- Understanding its customers' needs, and providing them with the highest quality, service, and value, allowing them to achieve their goals and market objectives.
- Creating a friendly, innovative, open workplace allowing all employees to reach their full potential and share in the success of the company.
- Developing long-term, mutually beneficial relationships with suppliers who can provide the resources necessary to meet the needs of the company and its customers.
- Managing the company on a basis of profitable controlled growth, sharing the rewards with those contributing to its success, and investing for the future.

Manufacturing Capability

Vigon International possesses extensive on-site manufacturing capability including vacuum distillations, extractions, reactions, liquid compounding, and emulsions. This capability allows Vigon to produce and offer a wide variety of products in virtually any quantity. In addition, our on-site process development lab allows us to add new products to our offering based on the broader needs of the market, or to custom manufacture based on the specific needs of our customers.

Strategic Partnerships

At the core of Vigon International's unique partnership based business model are the key partnerships that have been established with major multinational flavor and fragrance and ingredient manufacturers. These partnerships combine the product manufacturing expertise of the manufacturer with the marketing, sales, customer service and distribution expertise of the Vigon team.

Vigon International currently has strategic partnerships with both the fragrance and flavor divisions of Givaudan, the world's largest flavor and fragrance manufacturer based in Vernier, Switzerland. Since 1998, Vigon International has been responsible for marketing and supplying Givaudan's fragrance ingredients to a select group of customers in the United States and Canada. In 1999, Vigon began marketing and supplying Givaudan's flavor ingredients and compounds to flavor manufacturers in the United States. For more information about Givaudan, please visit their web site at www.givaudan.com.

In December of 2000, Vigon International established a strategic partnership with the Fine Chemicals Division of Degussa (now Evonik Industries), a global chemical manufacturer. As part of the partnership, Vigon markets and supplies a wide range of Evonik's intermediates to the flavor and fragrance market in the United States. For more information about Evonik, please visit their web site at **www.evonik.com**.

In 2004 Vigon International established a partnership with Rhodia Inc. (now Solvay), a leading global specialty chemicals manufacturer, for the management and supply of their flavor and fragrance ingredients to the flavor and fragrance industry. As part of this partnership, Vigon manages the sales, customer service, warehousing, and shipping of Solvay's flavor and fragrance ingredients to a select group of customers in the North American market. For more information about Solvay, please visit their web site at **www.solvay.com**.

At the outset of 2005, Vigon International established a strategic partnership with Symrise Inc., one of the world's top flavor and fragrance manufacturers, for the management and supply of the Symrise Aroma Chemicals to the flavor and fragrance industry. As part of this partnership, Vigon manages the sales, customer service, warehousing, and shipping of Symrise Aroma Chemicals to a select group of customers in the North American market. For more information about Symrise, please visit their web site at **www.symrise.com**.

In March 2006, Vigon International and Firmenich, one of the preeminent global leaders in the flavor and fragrance industry, created a strategic partnership for the management and supply of the Firmenich Ingredients to the North American marketplace. The partnership was established in order to provide the maximum level of service possible for the supply of the Firmenich Ingredients to the flavor and fragrance industry. As part of this partnership, Vigon manages the sales, customer service, warehousing, and shipping of the Firmenich Ingredients to a select group of customers in the North American market. For more information about Firmenich, please visit their web site at **www.firmenich.com**.

At the beginning of February 2007, Vigon established a partnership with BASF, the world's leading chemical company, in order to maximize the level of service that customers receive for the procurement of BASF's Aroma Chemicals in the flavor and fragrance industry. As part of this partnership, Vigon will be managing the sales, customer service, warehousing, and shipping of BASF Aroma Chemicals to a select group of flavor and fragrance customers in the North American market. For more information about BASF, please visit their web-site at **www.basf.com**

Food Safety Organization

HACCP/Food Safety Team

MEMBER	TITLE/ROLE	FOOD SAFETY TEAM ROLE	TRAINING
JOHN ROSS	Senior Quality Director	Deputy to FSTL and Member	PCQI/HACCP
DEB ABER	Food Safety Team Leader	Food Safety Team Leader	HACCP/PCQI/FSVP (FSPCA)
NICOLETTE DESOUZA	Lab and Food Safety Tech	Food Safety Team	Internal FS team Training
RANDY CORNELL	Production Supervisor	Member	Internal FS Team Training
MATT MACHALIK	Warehouse Manager	Member	HACCP
MARK PATNEY	Operations Manager	Member	Internal FS Team Training
DAVID SIEDT	Facilities Engineer – Process Engineer	Member	Internal FS Team Training
FELICIA PERRYMAN	Director of Quality Control	Visiting/Associate Member	GMP Training - HSI
LORI AUSTIN	Customer Service Manager	Visiting/Associate Member	GMP Training - HSI
DANNA WARD	Quality Systems Manager	Visiting/Associate Member	GMP Training - HSI
BILL BOWER	Purchasing Coordinator	Visiting/Associate Member	PCQI/HACCP/BPS

Organization Chart and Responsibility and Authority

See Reference- 06 and 07

HACCP Plan Revisions

Revision 7/30/2021- FST Review

1. New parent company (AZELIS)
2. Addition of new tanks, no changes to HACCP
3. New Process Engineer (Greg Brown)
4. New Junior Engineer (Mike Taenzer)
5. New EH&S Training Manager (Heidi Fleming)
6. Food Fraud and Defense Plan updated
7. New supplier risk assessments completed
8. New water lines to fill tanks directly in bld 3 and bld 5
9. New water access line in bld 2 and bld 5
10. New fire suppression system
11. New cameras in DC repack room
12. New 5 gallon filler
13. New automatic labeling systems
14. New external PG line installed
15. New allergen programming in SBT
16. Added allergen risk assessment

Revision 10/21/2020- FST Review

1. Addition of new blending tanks, no change to HACCP
2. Addition of new reaction tanks, no change to HACCP
3. Food Defense Plan updated
4. New Decernis software for food fraud investigations
5. Food fraud risk assessments completed
6. Addition of new Operations Manager (Mark Patney)
7. New insulation of pipes for condensation prevention
8. New drain systems in bld 3 and 5 installed
9. New CIP system for stainless steel totes
10. New Charm EM monitoring system in food safety
11. New Hygiena Touch ATP reader food safety
12. Food safety team members updated for 2020
13. New planning manager (Dan Meloro)
14. New purchasing analysist (Guiolber Diaz)
15. New HR manager (Gabrielle Cray)
16. New exhaust system bld 2
17. New double filtration system for wash extracts
18. New filtration in the DC repack room

Revision 6/21/19- FST Review

1. New dump station sifter installed in powder room
2. New dishwasher installed and validated in bld 3
3. New soap 812 for dishwasher
4. New stainless steel totes in use throughout buildings
5. New tanks- 3 cooling tanks 5 blending tanks
6. New homogenizer installed bld 5-including haccp plan
7. Haccp certification for several people
8. Food defense plan updated
9. Vigon at 110 employees
10. New safety manager (Charles Tuzzolo)
11. New autofiller installed
12. New PG tanks bld 5
13. New walk-in cooler outside bld 5
14. New OPRP on dump sifter
15. New Chief Operating Officer (Ken Wiecorek)
16. Bill Bower moved to purchasing
17. Added two new planners
18. Food safety team members updated for 2019

Revision 09/26/2018- FST Review 10/04/2018

1. Vigon is not at 95 Employees
2. Food Safety Team Members updated for 2018
3. Flow Diagrams changed and Receiving put on its own product profile
4. Additional equipment added to blending product profile for TFA
5. Receiving Product Profile Added
6. Receiving Product Profile Process Hazard Analysis Added
7. Addition of PG Distribution Tank and Bulk Receiving Added
8. Pre-weighs and Batching added to Powder Process Hazard Analysis
9. Tracegains Document Control System added
10. Glass and Brittle Plastics Log added to floor documents
11. Cani 702PW changed to Default soap under Cleaning Validation Program
12. Sensitizers removed from allergen program

Revision 09/27/2017- FST Review 09/29/2017

1. New Food Safety Team Member John McCabe: Associate Facilities Engineer
2. Biological Pathogens update on Hazard Assessment
    a. Reviewed during ENV Monitoring Validation per industry guidelines and FDA Articles. Pathogens of Concern are Listeria and Salmonella. Indicator testing through EB/Listeria Testing. **See Reference Environmental Monitoring Plan and Cleaning.**
3. Added 2'' and ¾' primary contact faucets for downpacks. Control Measure is to throw away after use.
4. Added Plastic 1 Gallon Jug Kit for new TFA customer and completed risk analysis.
5. SEC101 changed from Food Security Plan to Food Defense Plan
6. FDA Food Code Changed to 2013
7. Addition of Conditional Approval in TG for the Vendor Approval Program
8. Recall PRP now includes "Recall Notification of Interested Parties Document" to better facilitate external communication
9. Validations studies for Micro and Chemical (Allergen) cross contaminations added in Preventative Control Plan
10. Addition of ENV Monitoring Procedure to Preventative Control Programs Codex Alimentarius.
11. CCP#1 Filtration Change on CODEX for Production Packout Report. Filtration no longer on pre-post inspection due to length of WOs
12. 4 Head Fillers used for blending and compounding packouts.
13. Plastic Totes and Bag Inserts new packaging materials.
14. Change of Buckeye Soaps to CANI Soaps for odorous and tank cleaning
15. Addition of Micro testing services by Diebel Labs. ISO 17025 certified

Revision 10/21/2016- FST Minutes 10/28/2016

1. New Interactive Table of Contents
2. Food Safety Team Members updated with mention to role and training
3. Hazard Identification includes
    a. FDA guidance reference documentation
    b. Radiological Hazards
    c. EMA Hazards
4. Risk Assessment Template now includes PCP (Preventative Control Points)
5. Updated Raw Material Packaging Risk Assessment
6. Prerequisite Format Changed to get out of tabular form.
    a. Increased focus on references, records, and verification
    b. Addition of backup deputy
    c. Addition of PCP (Preventative Control Program)
7. Preventative Control Program master list follows Codex Alimentarius Guidelines
8. CCPs and OPRPs have been revised and have been changed to the following:
    a. CCP 1 Filtration and CCP 2 Metal Detection
    b. OPRP 1 Magnet
    c. Flow Diagrams have been updated
    d. Process Flow Hazard Analysis has been updated.
9. Included Finished Product Sampling into Process Flow Assessment
10. Process Flow Assessment now follows FSMA Guidelines
11. Flow Diagram Labeled and Inspection and

Hazard Identification and Risk Assessment

THE PRESENCE, INTRODUCTION, GROWTH AND SURVIVAL OF ALL HAZARDS THAT COULD AFFECT THE SAFETY OF THE PRODUCT OR WHICH MAY CAUSE THE PRODUCT TO BE ADULTERATED, AND ALL EVENTUALITIES INCLUDING THE POTENTIAL FOR DELIBERATE CONTAMINATION OR ADULTERATION OF THE PRODUCT WILL BE CONSIDERED. SOURCE OF SUCH HAZARDS ARE:

BIOLOGICAL: PATHOGENS AND SPOILAGE PER THE FDA BAD BUG BOOK; DEIBEL LABORATORIES INGREDIENT RISK ASSESSMENT; SUPPLIER HACCP, ITEM QUESTIONNAIRE, AND SPEC SHEETS

POTENTIAL PATHOGENS: SALMONELLA, LISTERIA, STAPH AUREUS, E. COLI, B. CEREUS, ALICYCLOBACILLIUS, LACTIC ACID BACTERIA

SPOILAGE: OSMOPHILIC YEAST

PHYSICAL: PER CPG SEC 555.425 FDA HEALTH HAZARD EVALUATION BOARD

HAZARDOUS FOREIGN MATERIAL: (FOREIGN MATERIAL BETWEEN 7-25MM AND GLASS AND BRITTLE PLASTIC)

NON HAZARDOUS FOREIGN MATERIAL: METAL, WOOD, PLASTIC, RUBBER, MACHINE/EQUIPMENT PARTS, PACKAGING MATERIAL, PERSONAL ITEMS, OR ANY OTHER FOREIGN MATERIAL <7MM AND >25MM

CHEMICAL: PER FOOD ALLERGEN PARTNERSHIP (FDA GUIDANCE DOCUMENTATION)

MYCOTOXINS (ASPERGILLUS, OCHRATOXIN, DEOXYNIVALENOL) ALLERGENS, HEAVY METALS (CADMIUM, LEAD, ARESENIC), PESTICIDES, DECOMPOSITION, UNAPPROVED ADDITIVES (CLEANING/MX CHEMICALS, COLORS)

RADIOLOGICAL: PER EPA STANDARDS FOR WELL WATER CONTAMINATES

CONTAMINATED WATER (MUNICIPAL), NUCLEAR FALLOUT, NATURAL DISASTER

ECONOMICALLY MOTIVATED ADULTERATION: PER INDUSTRY SPECIFIC DETAIL AND FDA ANNOUNCEMENT; DECERNIS TRACKING SYSTEM

PRODUCT SPECIFIC BASED ON RELATIVE VALUE AND EMA HISTORY OF RAW MATERIALS OR FINISHED PRODUCT

DEFINING RISK AND DETERMINING CPC, OPRP, AND PRP

*FDA PRINCIPLES AND APPLICATION GUIDELINES <FDA.GOV/FOOD/GUIDANCEREGULATION/DEFAULT.HTM>

Significance Risk Matrix					
	Frequency (Likelihood):				
Severity	A) Common	B) Known to occur	C) Could occur	D) Not Expected to Occur	E) Practically impossible
1) Fatality	1	2	4	7	11
2) Serious Illness	3	5	8	12	16
3) Product recall	6	9	13	17	20
4) Customer Complaint	10	14	18	21	23
5) Insignificant	15	19	22	24	25

		Monitoring Program
High Risk	1-10	PCP/CCP*
Moderate Risk	11-15	OPRP
Low Risk	16-25	PRP/GMP
No Risk	16-25	GMP/NA

Raw Material Hazard Analysis

Risk Assessment Based on Raw Material Category

Raw Material Category	*Hazards Applicable*	*Potential Hazards for Category*	*Hazard Likelihood*	*Hazard Severity*	*Significant Hazards*	*Control Measures*	*Comments*
Flavor (Liquids)- Sensory Impression on a food	Physical	P: metal, glass, plastic, wood, stone, twigs	P: Known to Occur	P: Product Recall	P: Yes (PCP)	**FSVP, Supplier approval program**	**Haccp review for controls**
	Chemical	C: Heavy Metals, Additives, Mycotoxins, Cleaning Chemicals	C: Could Occur	C: Product Recall	C: Yes (PCP)	**COA and Lot RM Testing**	**COA testing and in house quality testing**
		C: Allergens	C: Known to occur	C: Product Recall	C: Yes (PCP)	**FSVP, supplier approval program, Lot RM Testing**	**Inspection or raw materials and labels**
	Microbiological	M: Staph aureus, E. Coli cryptosporidium, Salmonella, Listeria, Bacillus Cereus, C. Perfringens, Trypanosoma cruzi (Chagas) (Acai only)	M: could occur	M: Product Recall	M: Yes (PCP)	**FSVP, COA, supplier approval program n/a**	**HACCP reviewed for controls**
	Radiological	R: Radionuclides: Radium-226, Radium-228, Uranium-235, Uranium- 238	R: Pract. Impossible	R: Product Recall	R: No	**FSVP. Supplier approval COA, Lot testing,**	**Suppliers not in geographic areas of radionuclide hazards**
	EMA Hazards	E: Vanilla, mustard oil, Turmeric, Paprika	E: Not Expected	E: Customer Complaint	E: No	**FSVP, supplier approval,**	**Some tests required on COA**

(Powders)	Physical	P: Metal, plastic	P: Known to occur	P: Product recall	P: Yes (PCP)	**FSVP, supplier approval, RM lot testing,**	**HACCP review for controls**
	Chemical	C: Allergens, residual soap or lubricants, Mycotoxins, melamine	C: Known to Occur	C: Product Recall	C: Yes (PCP)	**FSVP, supplier approval, COA**	**Truck inspections and label checking**
	Microbiological	M: Salmonella, Staph aureus Enterotoxin, E. coli, Listeria monocytogens,	M: Known to Occur	M: Product Recall	M: Yes (PCP)	**COA, Supplier Approval Program**	**Micro testing later step**
	Radiological	R: Radionuclides	R: Pract. Impossible	R: Product Recall	R: No	**Supplier Approval Program**	**No suppliers near nuclear reactors or disaster sites. It is assessed on supplier questionnaires**
	EMA Hazards	E: Vanillin adulteration, whey powder	E: Known to Occur	E: Customer Complaint	E: Yes (PCP)	**Supplier approval, COA, RM lot testing**	**HACCP Reviewed for controls Truck inspection and GC testing**
Cosmetic- Applied to body or skin	Physical	P: Metal or plastic	P: Could Occur	P: Customer Complaint	P: No (GMP)	**FSVP, Supplier approval, RM lot testing**	
	Chemical	C: Allergen, residual solvents	C: Could Occur	C: Customer Complaint	C: Yes (PCP)		
	Microbiological	M: Microbiological	M: Not Expected	M: Customer Complaint	M: No (GMP)		
Fragrance NF Grade	Chemical	C: Chemical Contamination	C: Not Expected	C: Customer Complaint	C: No (GMP)		**Regulation FD&C Act not FSMA No Regulation**

***Note:** Every Raw Material Item approved by Vigon has a risk assessment through the Item Assessment Form.

Risk Assessment Based on Supplier Relationships Food Status

Supplier Scenario	*Type of Relationship with Supplier*	*Does the Supplier have a GFSI Cert?*	*Material must be GRAS compliant and a recall program?*	*Does the Supplier have Hazard Controls?*	*Will Vigon Control any hazards?*	*Risk Assessment Determination*	*Verification based by Risk*
GFSI Food Grade Partner	Distribution	Yes	Yes	Yes	No	Low	Electronic Approval via Tracegains
Non GFSI Food Grade Partner	Distribution or MFG	No	Yes	Yes/Some	Yes/Some	Medium	Conditional Approval in TG or Documented Codex Aliment.
MFG for Partner	Toll Work	N/A	Yes	no	Yes	Low	Electronic Approval via Tracegains
Non Partner GFSI Food Grade Supplier	Distribute or Manufacture	Yes	Yes	Yes	No (depending on process Flow)	Low	Electronic Approval via Tracegains
Non Partner Non GFSI Food Grade Supplier	Distribute or Manufacture	No	Yes	Yes/Some	Yes/Some	Medium	Food Safety Team Leader Approval
Non Food Grade Supplier	Manufacture /Technical Grade	No	Yes	Some/No	All/Some	High	Request Follow up docs or Audit. Vigon Controls CCPs

Risk Assessment for Packaging Material

Raw Material Category	*Hazards Applicable*	*Potential Hazards for Category*	*Hazard Likelihood*	*Hazard Severity*	*Significant Hazards*	*Control Measures*	*Comments*
Primary Packaging-Steel Drums	Physical Chemical Microbiological Radiological EMA Hazards	P: Drum Liner, Bung Liner C: Non Food Grade additives M: N/A R: Radionuclides E: N/A	P: Known to Occur C: Not Expected M: N/A R: N/A E: N/A	P: Customer Complaint C: Product Recall M: N/A R: N/A E: N/A	P: No (PRP) C: No (PRP) M: No R: No E: No	**Visual Inspect** **FG LOGs**	**Filter if Found** **21CFR172 (Liner)** **No Ionizing Radiation**
Primary Packaging-Plastic Drums	Physical Chemical Chemical Microbiological Radiological EMA Hazards	P: Plastic C: Non Food Grade additives C: Odor Leaching M: N/A R: Radionuclides E: N/A	P: Not Expected C: Not Expected C: Could Occur M: N/A R: N/A E: N/A	P: Customer Complaint C: Product Recall C: Customer Complaint M: N/A R: N/A E: N/A	P: No (GMP) C: No (PRP) C: No (PRP) M: No R: No E: No	**Visual Inspect** **FG LOGs** **RM Inspection**	**Filter if Found** **21CFR174** **HDPE smell Leach** **No Ionizing Radiation**
Primary Packaging-Metal Pails /Canisters	Physical Chemical Microbiological Radiological EMA Hazards	P: Drum Liner, Bung Liner C: Non Food Grade additives M: N/A R: Radionuclides E: N/A	P: Not Expected C: Not Expected M: N/A R: N/A E: N/A	P: Customer Complaint C: Product Recall M: N/A R: N/A E: N/A	P: No (PRP) C: No (PRP) M: No R: No E: No	**Visual Inspect** **FG LOGs**	**Filter if Found** **21CFR172 (Liner)** **No Ionizing Radiation**
Primary Packaging-Plastic Pails /Canisters	Physical Chemical Chemical Microbiological Radiological EMA Hazards	P: Plastic C: Non Food Grade additives C: Odor Leaching M: N/A R: Radionuclides E: N/A	P: Not Expected C: Not Expected C: Could Occur M: N/A R: N/A E: N/A	P: Customer Complaint C: Product Recall C: Customer Complaint M: N/A R: N/A E: N/A	P: No (GMP) C: No (PRP) C: No (PRP) M: No R: No E: No	**Visual Inspect** **FG LOGs** **RM Inspection**	**Filter if Found** **21CFR174** **HDPE smell Leach** **No Ionizing Radiation**

1 Gallon Plastic Jug Kit	Physical	P: Plastic Around Spout	P: Known To Occur	P: Customer Complaint	P: No (GMP)	**Visual Inspect**	**Filter if Found**
	Chemical	C: Non Food Grade Additive	C: Not Expected	C: Product Recall	C: No (PRP)	**FG LOGs**	**21CFR174**
	Microbiological	M: N/A	M: N/A	M: N/A	M: No		
	Radiological	R: Radionuclides	R: N/A	R: N/A	R: No		**No Ionizing Radiation**
	EMA Hazards	E: N/A	E: N/A	E: N/A	E: No		
Primary Packaging-Aluminum Canisters	Physical	P: Cap FM	P: Not Expected	P: Customer Complaint	P: No (GMP)	**Visual Inspect**	**Filter if Found**
	Chemical	C: Non Food Grade additives	C: Not Expected	C: Product Recall	C: No (PRP)	**FG LOGs**	**21CFR174**
	Microbiological	M: N/A	M: N/A	M: N/A	M: No		
	Radiological	R: Radionuclides	R: N/A	R: N/A	R: No		**No Ionizing Radiation**
	EMA Hazards	E: N/A	E: N/A	E: N/A	E: No		
Primary Packaging-Totes (Plastic)	Physical	P: Plastic	P: Not Expected	P: Customer Complaint	P: No (GMP)	**Visual Inspect**	**Filter if Found**
	Chemical	C: Non Food Grade additives	C: Not Expected	C: Product Recall	C: No (PRP)	**FG LOGs**	**21CFR174**
	Chemical	C: Odor Leaching	C: Could Occur	C: Customer Complaint	C: No (PRP)	**RM Inspection**	**HDPE smell Leach**
	Microbiological	M: N/A	M: N/A	M: N/A	M: No		
	Radiological	R: Radionuclides	R: N/A	R: N/A	R: No		**No Ionizing Radiation**
	EMA Hazards	E: N/A	E: N/A	E: N/A	E: No		
Primary Packaging-Closures (Bungs, Cap, Screw Cap, Tight Head,Plugs)	Physical	P: Plastic or Metal Residue	P: Not Expected	P: Customer Complaint	P: No (GMP)	**Visual Inspect**	**Filter if Found**
	Chemical	C: Non Food Grade additives	C: Not Expected	C: Product Recall	C: No (PRP)	**FG LOGs**	**21CFR174**
	Microbiological	M: N/A	M: N/A	M: N/A	M: No		
	Radiological	R: Radionuclides	R: N/A	R: N/A	R: No		**No Ionizing Radiation**
	EMA Hazards	E: N/A	E: N/A	E: N/A	E: No		
Primary Packaging-Gaskets (Resin,Plastic,HDPE)	Physical	P: Plastic or Metal Residue	P: Not Expected	P: Customer Complaint	P: No (GMP)	**Visual Inspect**	**Filter if Found**
	Chemical	C: Non Food Grade additives	C: Not Expected	C: Product Recall	C: No (PRP)	**FG LOGs**	**21cfr175**
	Chemical	C: Odor Leaching	C: Not Expected	C: Customer Complaint	C: No (GMP)	**RM Inspection**	
	Microbiological	M: N/A	M: N/A	M: N/A	M: No		
	Radiological	R: Radionuclides	R: N/A	R: N/A	R: No		**No Ionizing Radiation**
	EMA Hazards	E: N/A	E: N/A	E: N/A	E: No		

Food Contact Faucets (2'' and ¾'')	Physical Chemical Microbiological Radiological EMA Hazards	P: Paper, Plastic C: Odor Leaching M: N/A R: Radionuclides E: N/A	P: Not Expected C: Known to Occur M: N/A R: N/A E: N/A	P: Customer Complaint C: Customer Complaint M: N/A R: N/A E: N/A	P: No (GMP) C: No (GMP) M: No R: No E: No	**Visual Inspect** **Throw Away**	**Filter if Found** **No Ionizing Radiation**
Primary Packaging-Fiber Drums and Plastic Bags	Physical Chemical Microbiological Radiological EMA Hazards	P: Paper, Plastic C: Non Food Grade additives M: N/A R: Radionuclides E: N/A	P: Not Expected C: Not Expected M: N/A R: N/A E: N/A	P: Customer Complaint C: Product Recall M: N/A R: N/A E: N/A	P: No (GMP) C: No (PRP) M: No R: No E: No	**Visual Inspect** **FG LOGs**	**Filter if Found** **21CFR176 and 174** **No Ionizing Radiation**
Secondary Packaging-Wrap/Boxes/Tape/ Logo & Security Caps	Physical Chemical Microbiological Radiological EMA Hazards	P: Paper, Plastic C: Non Food Grade additives M: N/A R: Radionuclides E: N/A	P: Not Expected C: Pract. Impossible M: N/A R: N/A E: N/A	P: Customer Complaint C: Product Recall M: N/A R: N/A E: N/A	P: No (GMP) C: No (GMP) M: No R: No E: No	**Visual Inspect** **FG LOGs**	**Filter if Found** **No Ionizing Radiation**

Prerequisite Programs

Construction and Layout of Buildings

Responsibility: Facilities Manager, Food Safety Team Leader (Deputy)

ISO/TS Reference:

1.1 General Requirements
1.2 Environment
1.3 Location of Establishments

Program Description: Buildings shall be designed, constructed and maintained in a manner appropriate to the nature of the processing operations to be carried out, the food safety hazards associated with those operations and the potential sources of contamination from the plant environment. Buildings shall be of durable construction which present no hazard to the product

References/Records: 22-25 Construction and Layout of Buildings, FDA Food Code 2013-Chapter-6 Physical Facilities, Risk Assessment of Hazards from Local Environments, Risk Assessment of Environmental Areas, 22-10F1 Environmental Sampling Map, SEC101 Food Defense Plan, VIR Audit Report, Internal Yearly Audit Report, Yearly Security Audit Report

Verification: Internal Yearly Audit, Internal Yearly Security Audit, Monthly VIR Audit

Layout of Premise and Workspace

Responsibility: Facilities Manager, Food Safety Team Leader (Deputy)

ISO/TS Reference:

5.1 General requirements

5.2 Internal design, layout, and traffic patterns

5.3 Internal structures and fittings

5.4 Location of Equipment

5.5 Laboratory Facilities

5.6 Vending Machines

5.7 Storage of food, packaging materials, ingredients, and non-food chemicals

Program Description: Internal layouts shall be designed, constructed, and maintained to facilitate good hygiene and manufacturing practices. The movement patterns of materials, products and people, and the layout of equipment shall be designed to protect against potential contamination sources

References/Records: 22-25 Internal Design and Workspace flow, FDA Food Code 2013-Chapter-6 Physical Facilities, Raw Material/Forklift traffic allergen/waste storage Flow diagrams, 12-01 Lab Inspection and Test Status, Vending Machine Risk Assessment, Storage Perimeter Risk Assessment, Temperature and Humidity Logs, 15-02 Handling Storage and Preservation, 22-11 Chemical Control Program, 22-08 New Equipment Approval Plan, Yearly Internal Audit Report, VIR Inspection Reports

Verification: Internal Yearly Audit, Monthly VIR Audit

Utilities – Air, Water, Energy

Responsibility: Facilities Manager, Food Safety Team Leader (Deputy)

ISO/TS Reference:

6.1 General requirements

6.2 Water Supply

6.3 Boiler Chemicals

6.4 Air Quality and Ventilation

6.5 Compressed Air and Other Gasses

6.6 Lighting

Program Description: The provision and distribution routes for utilities to and around processing and storage areas shall be designed to minimize the risk of product contamination. Utilities' quality shall be monitored to minimize product contamination risk.

References/Records: 22-16 Utilities – Air/Water/Energy, Potable Water Source Diagram, Prosser Lab Water Microbiological and Heavy Metal Testing, EPA Water Regulations Chapter 109 Section 2.1, Proasys Boiler Water Testing, Backflow Prevention Testing, Air Care and Restoration Compressed and Ambient Air Testing, 22-05F2Glass and Brittle Plastic Master List, Broadhead Creek Water Quality Report, 22-16-01 Adverse Water Plan, Certificate of Conformity (Compressed Lab Gases), 22-05 Glass and Brittle Plastic

Verification: Internal Yearly Audit, Monthly VIR Audit, Broadhead Creek Annual Water Quality Report, Monthly External Lab Water Analysis, Monthly Steam Water Report, Yearly Glass and Brittle Plastic Report, Yearly Certificate of Conformity (Compressed Lab Gases)

Waste Disposal

Responsibility: Facilities Manager, Food Safety Team Leader (Deputy)

ISO/TS Reference:

6.1 General requirements

6.2 Containers for waste and inedible or hazardous substances

6.3 Waste management and removal

6.4 Drains and Drainage

Program Description: Systems shall be in place to ensure that waste materials are identified, collected, removed, and disposed of in a manner which prevents contamination of products or production areas

References/Records: 22-24 Waste Management Program, Chemical Waste Storage Flow Diagram, 22-24f Waste Logs, Waste Manifest Records, Approved Waste Collectors 40cfr264.12 and .13, 22-13 Floor Drains, 22-05 Company Housekeeping, 22-10 Environmental Sampling Plan

Verification: Internal Yearly Audit, Monthly VIR Audit, Monthly Environmental Monitoring Swabs, Weekly Housekeeping Logs

Equipment Suitability, Cleaning, and Maintenance

Responsibility: Facilities Manager, Food Safety Team Leader (Deputy)

ISO/TS Reference:

8.1 General Requirements

8.2 Hygienic Design

8.3 Product Contact Surfaces

8.4 Temperature Control and Monitoring Equipment

8.5 Cleaning Plant, Utensils, and Equipment

8.6 Preventative and Corrective Maintenance

Program Description: Food contact equipment shall be designed and constructed to facilitate cleaning, disinfection, and maintenance. Contact Surfaces shall not be affected, or be affected by, the intended product or cleaning system. Food contact Equipment shall be constructed of durable materials able to resist repeated cleaning.

References/Records: 22-08f1 New Equipment Approval Form, 21CFR174/177/178, Certificate of Conformances for Food Grade Equipment, 22-19 Refrigeration Monitoring, 22-19F Refrigeration Monitoring Form, 22-06-02 Cleaning Procedure – DishWashing, OPM or PB Forms (Cleaning), 22-06F1 Sanitation Swabbing Report, 22-06-01 Cleaning Verification Monitoring, 22-04F1 DC Cleaning Logs, 22-04 Company Housekeeping

Verification: Internal Yearly Audit, Monthly VIR Audit, 22-19f Refrigeration Monitoring Form, Dishwashing Training, Sanitation Swabbing Signoff, DC and MFG Cleaning Logs,

Management of Purchased Materials (Preventative Control Program)

Responsibility: Procurement, Food Safety Team Leader (Deputy)

ISO/TS Reference:

9.1 General Requirements

9.2 Selection and Management of Suppliers (Supply Chain Controls)

9.3 Incoming Material Requirements (Raw/Ingredients/Packaging) (Supply Chain Controls)

Program Description: Purchasing of materials which impact food safety shall be controlled to ensure that the suppliers used have the capability to meet the specified requirements. The conformance of incoming materials to specified requirements shall be verified.

References/Records: 06-01 Vendor Approval, 06-01-02F Supplier Questionnaire, 06-01-02F2 C-TPAT Questionnaire, 06-01-02F6 Item Questionnaire, Tracegains Approval Process, FSMA FSVP, Yearly Materials Management Review, Vendor Compliance Audits, 10-01-01 Receiving and Inspecting Incoming Materials, 13-01-06 Damaged Goods

Monitoring: Quarterly Vendor Review, Customer Complaint Annual Trending

Corrective Actions: Sugar and PRR Quest CAPAS. Reassessment of Supplier or Item Classification (Conditional Approval)

Verification: Internal Yearly Audit, Tracegains Program, Yearly Vendor Management Review, Vendor Compliance Audits, Vehicle Inspection Logs, Vendor Deficiency Report.

Measures for Prevention of Cross-Contamination (Preventative Control Program)

Responsibility: Food Safety Team Leader, Senior Director of Technical Services (Deputy)

ISO/TS Reference:

10.2 Microbiological Cross-Contamination (Sanitation Controls PCP)

10.3 Allergen Management (Risk Assessment Below) (Food Allergen PCP)

10.4 Physical Contamination (Process Controls OPRP)

Program Description: Programs shall be in place to prevent, control, and detect contamination. Measures to prevent physical, allergen, and microbiological contaminations shall be included.

References/Records: 22-10 Environmental Sampling Plan, 22-10F1 ENV Sampling Map, ENV Monitoring Risk Assessment, 22-09 Allergen Policy, Allergen Cleaning Validation, FALCPA FDA, 22-06F1 Sanitation Swabbing Report, 22-06-01 Cleaning Verification Monitoring, 22-07 Color Coding, 22-05 Glass and Brittle Plastic, 22-05F2 Glass and Brittle Plastic Master List, 22-03 Workwear and Protective Clothing Policy, 22-18F Food Safety Exception Form

Monitoring: QC Tech or FS Team Leader will randomly swab 5-10 zone 1 product contact surfaces in a 10x10cm^2 surface area after a microsensitive or Allergen Work Order.

Corrective Actions: Re-Clean and Re-swab after any failures. Log and assess corrective actions at Quarterly Swabbing Trending Report. Food Safety Exception Reports

Verification: Internal Yearly Audit, Monthly Internal VIR Audits, Yearly Glass and Brittle Plastic Audit, Sanitation Swabbing Records, Environmental Monitoring Records, Pre and Post Equipment Inspection, Filtration Inspection Verification, Magnet Verification.

Validations: ENV Monitoring Plan and Cleaning Study, Allergen Cross Contamination of Milk Powder Study, Magnet Pull Testing OPRP

Allergen Risk Assessment						**2. Date of assessment/review:**		**4/30/2021**	
3. Assessment carried out by: Deborah Aber					**4. Allergens onsite: Dairy, Tree nut (oils), Peanut (oils), Wheat/Gluten, Soy, Sesame, Celery, Sulfites, Mustard.**				
5. Specific Hazard: Allergen Cross Contamination									
6. Specific Hazard					**Contamination of other raw materials, packaging or finished products due to allergen production.**				
Step:	**Hazards**	**8. Initial Risk Evaluation**			9. **Controls – existing & further required, including addressing any special risk groups**	**10.Remaining Risk Evaluation**			
		Likelihood	**Severity**	**Risk**		**Likelihood**	**Severity**	**Risk**	
Raw material receipt	Cross contamination of allergens to non-allergens from punctured packaging.	**L**	**M**	**A**	Truck inspection on arrival	**L**	**L**	**L**	
	Incorrect labelling on arrival	**L**	**M**	**A**	Labelling procedure Supplier approval program	**L**	**L**	**L**	
		M	**M**	**M**	Allergen storage policy	**L**	**M**	**A**	

Raw material Storage	Cross contamination from split bags or spills	**M**	**M**	**A**	Allergen storage lock out, like with like only	**L**	**L**	**A**
Raw material Staging	Raw material pallets for work orders mixed up	**L**	**M**	**A**	All pallets arranged for work orders have work order # stickers attached.	**L**	**M**	**A**
		L	**M**	**A**	All work order products are scanned into tank. If material does not belong system will not let it get scanned in	**L**	**L**	**L**
Ingredient Charging	Dust generated from powder dispensing	**H**	**M**	**I**	Separate room for powder allergens Exterior powder floors cleaned daily	**L**	**M**	**A**
	Spills of liquid allergens during dispensing	**M**	**M**	**A**	Allergen spill control procedure	**L**	**L**	**L**

Production	Ingredient will come into direct contact with utensils, pumps, filters, and tanks.	**H**	**H**	**I**	All equipment used for allergens are labelled with allergen sticker. Tanks with allergens are digitally locked out. All items are cleaned and allergen swabbed. Food safety releases tanks or equipment after passing swab. Sanitation policy and cleaning validations.	**L**	**M**	**A**
Packaging	Product goes directly from tank to drums or jerry cans. Possible spill.	**L**	**L**	**L**	Allergen spill control procedure	**L**	**L**	**L**
Labelling	Incorrect product labelling, does not list allergen	**M**	**H**	**H**	Labelling procedure and sign off to ensure correct labels are placed on packaging.	**L**	**H**	**A**
Finished Products Storage	Cross contamination from broken bags or containers	**M**	**M**	**A**	Storage policy	**L**	**M**	**L**

Finished Product Shipping	Cross contamination from dirty truck.	**L**	**M**	**A**	Truck inspections	**L**	**L**	**L**
Cleaning **Utensils**	Contamination during cleaning of utensils.	**H**	**H**	**I**	Color coded cleaning brushes, employee training program. Utensils swabbed by food safety when clean. .	**L**	**M**	**A**
Cafe	Anaphylactic reaction	**M**	**M**	**A**	Site induction includes allergen awareness.	**L**	**M**	**A**
	Cross contamination of products from Allergens used in Canteen area	**L**	**M**	**A**	Site induction includes allergen awareness and food safety. Wash hands before entering production facility. No food permitted on production floor	**L**	**L**	**L**
Visitors / New Employees	Anaphylactic reaction	**M**	**M**	**A**	Site induction procedures and allergen awareness training. Ascertain if visitors or new employees have food allergens Visitors are accompanied by Vigon employees	**L**	**M**	**A**

Likelihood Definitions:	**Severity Definitions:**	**Risk Definitions:**
Extremely Unlikely (LOW) Very remote chance of occurrence, say once every few years or every few thousand events	Slightly Harmful (LOW) Calculated from RSSL	**Low** No additional controls required.
Unlikely (MED) Chance of occurrence in the order of up to once per production run	Harmful (MED) Could lead to contamination of other products and or contact with operatives	**Acceptable [Medium]** Subject to following the defined precautions and controls.
Likely (HIGH) Chance of occurrence more frequent than once every production run	Extremely Harmful (HIGH) Would lead to contamination and or contact with operative	**Intolerable [High]** **Work should not be started or halted until risk is reduced to Acceptable [Medium] or Low**

	Severity:		
Likelihood:	Slightly **Harmful (LOW)**	**Harmful (MED)**	**Extremely Harmful (HIGH)**
Extremely **Unlikely (LOW)**	Low	**Acceptable [Medium]**	**Acceptable [Medium]**
Unlikely (MED)	**Acceptable [Medium]**	**Intolerable [High]**	**Intolerable [High]**
Likely (HIGH)	**Intolerable [High]**	**Intolerable [High]**	**Intolerable [High]**

Cleaning and Sanitizing (Preventative Control Programs)

Responsibility: Food Safety Team Leader, Senior Director of Technical Services (Deputy)

ISO/TS Reference:

11.1 General Requirements

11.2 Cleaning and Sanitizing Agents and Tools (Sanitation Controls PCP)

11.3 Cleaning in Place (CIP) Systems

11.4 Monitoring Sanitation Effectiveness

Program Description: Cleaning and Sanitizing programs shall be established to ensure that food processing equipment and environment are maintained in a hygienic condition. Programs shall be monitored for continued suitability and effectiveness.

References/Records: 22-06-01 Internal Cleaning Verification, 22-06-02 DishWashing, 22-22 Chemical Control: Food Grade Cleaning Chemicals, 22-04 Company Housekeeping, 22-04-F1 DC Cleaning Logs, 22-06F2 Powder Room Cleaning Log, WO-Pre/Post Clean Logs, 09-01-01 Liquid Blends, 09-01-02 RD, 09-01-05 Powder Blending, PB-01

Monitoring: QC Tech or FS Team Leader will randomly swab 5-10 zone 1 product contact surfaces in a 10x10cm^2 surface area after a microsensitive or Allergen Work Order.

Corrective Actions: Re-Clean and Re-swab after any failures. Log and assess corrective actions at Quarterly Swabbing Trending Report

Verification: Internal Yearly Audit, Monthly Internal VIR Audits, Food Grade Chemical LOG or Cert, Company Housekeeping Logs, Pre-Post Inspection Logs, Quarterly ENV and Cleaning Validation Reports, Sanitation Swabbing Report

Pest Control (Preventive Control Program)

Responsibility: Erhlich Pest Control Company, Food Safety Team Leader and Facilities Manager (Deputy)

ISO/TS Reference:

12.1 General Requirements

12.2 Pest Control Programs

12.3 Preventing Access

12.4 Harborage and Infestations

12.5 Monitoring and Detection

12.6 Eradication

Program Description: Hygiene, cleaning, incoming material inspection and monitoring procedures shall be implemented to avoid creating an environment conducive to pest activity

References/Records: 22-02 Pest Control, 22-04 Company Housekeeping, 22-04-F1 DC Cleaning Logs, Pest Location Map

Verification: Internal Yearly Audit, Monthly Internal VIR Audits, Quarterly Trending Reports, Housekeeping Logs,

Personnel Hygiene and Employee Facilities

Responsibility: Food Safety Team Leader, Facilities Manager (Deputy)

ISO/TS Reference:

13.1 General Requirements

13.2 Personnel hygiene facilities and toilets

13.3 Staff Canteens and designated eating areas

13.4 Workwear and protective clothing

13.5 Health Status

13.6 Illness and Injuries

13.7 Personal Cleanliness

13.8 Personal Behavior

Program Description: Requirements for personal hygiene and behaviors proportional to the hazards posed to the process area or products shall be established and documented. All personnel, visitors, and contractors shall be required to comply with the documented requirements.

References/Records: 22-01 Personnel Hygiene and Employee Facilities, 22-03 Workwear and Protective Clothing, Hair and Beard Net Risk Assessment,

Verification: Internal Yearly Audit, Monthly Internal VIR Audits, Quarterly Trending Reports, Housekeeping Logs,

Rework (Recharge)

Responsibility: Senior Director of Technical Services, Food Safety Team Leader (Deputy)

ISO/TS Reference:

14.1 General Requirements

14.2 Storage, ID, and Traceability

12.3 Rework Usage

Program Description: Rework shall be stored, handled and used in such a way that product safety, quality, traceability, and regulatory compliance are maintained

References/Records: 13-01-07 Rework, 15-02 Handling Storage and Preservation, 10-01 Inspection and Test Procedure, 13-01-01 Tagging System for Nonconformances,13-01-02 Review and Disposition of Nonconformance, 22-09 Allergen Policy

Verification: Internal Yearly Audit, Monthly Internal VIR Audits,

Product Recall Procedures (Preventative Control Program)

Responsibility: Food Safety Team Leader, Senior Director, Technical Services (Deputy)

ISO/TS Reference:

15.1 General Requirements

15.2 Product Recall Requirement

Program Description: Systems shall be in place to ensure that products failing to meet required food safety standards can be identified, located, and removed from all necessary points of the Supply Chain

References/Records: SE_0038_SFTY Emergency Contact List and Emergency Contact Cards, SUGAR Customer Database, TRACEGAINS Supplier Database, 13-01-03 Product Recall, 13-01-03F2 Product Recall Report. 13-01-03F3 (Recall Notification of Interested Parties)

Monitoring: Yearly Mock Recall Exercises for forward and backward traceability.

Corrective Actions: CAPA initiated and President and FS Team Involvement

Verification: Internal Yearly Audit, Previous Mock Recall Trace Exercises Udrive>FS Team Folder> Audits> Internal Audits>Mock Recalls

Warehousing

Responsibility: Warehouse Manager, Food Safety Team Leader (Deputy)

ISO/TS Reference:

16.1 General Requirements

16.2 Warehousing Requirements

16.3 Vehicles, Conveyances, and Containers

Program Description: Materials and products shall be stored in a clean, dry, well-ventilated spaces protected from dust, condensation, fumes, odors, or other sources of contamination

References/Records: 15-02 Handling, Storage, and Preservation, 22-19 Refrigeration Monitoring, 22-19F Refrigeration Monitoring Form, 22-11 Chemical Control Program, 13-01 Control of Nonconforming product, 22-24 Waste Management Procedure, 13-01-01 Tagging of NC Product, 15-02 Handling, Storage, and Preservation, 10-01 Inspection and Test Procedure, 10-01-01 Receiving and Inspection Materials, 10-01-01F Summary of Vendor Requirements

Verification: Internal Yearly Audit, Monthly VIR Audit, Vehicle Inspection Logs,

Product Information and Consumer Awareness

Responsibility: Regulatory Manager and Sr. Director, Technical Services, Food Safety Team Leader (Deputy)

ISO/TS Reference:

17 Product Information and Consumer Awareness

Program Description: Information shall be presented to consumers in such a way to enable them to understand its importance and make informed choices.

References/Records: Vigon Website for all Item Documentation, 08-01-02 Labeling, Item Documentation through Tracegains

Verification: Internal Yearly Audit, Monthly VIR Audit, Customer Requests Trending

Food Defense, EMA, Biovigilance, and Bioterrorism

Responsibility: Food Safety Team Leader, Facilities Manager (Deputy)

ISO/TS Reference:

18.1 General Requirements

18.2 Access Controls

Program Description: Each Establishment shall assess the hazards to products posed by potential acts of sabotage, vandalism, terrorism, or economic adulteration, and shall put in place proportional protective measures.

References/Records: Food Defense Plan, Food Security Training, SEC 101F1/2/3 Facility Security Checklists, Bi-Annual FDA Registration

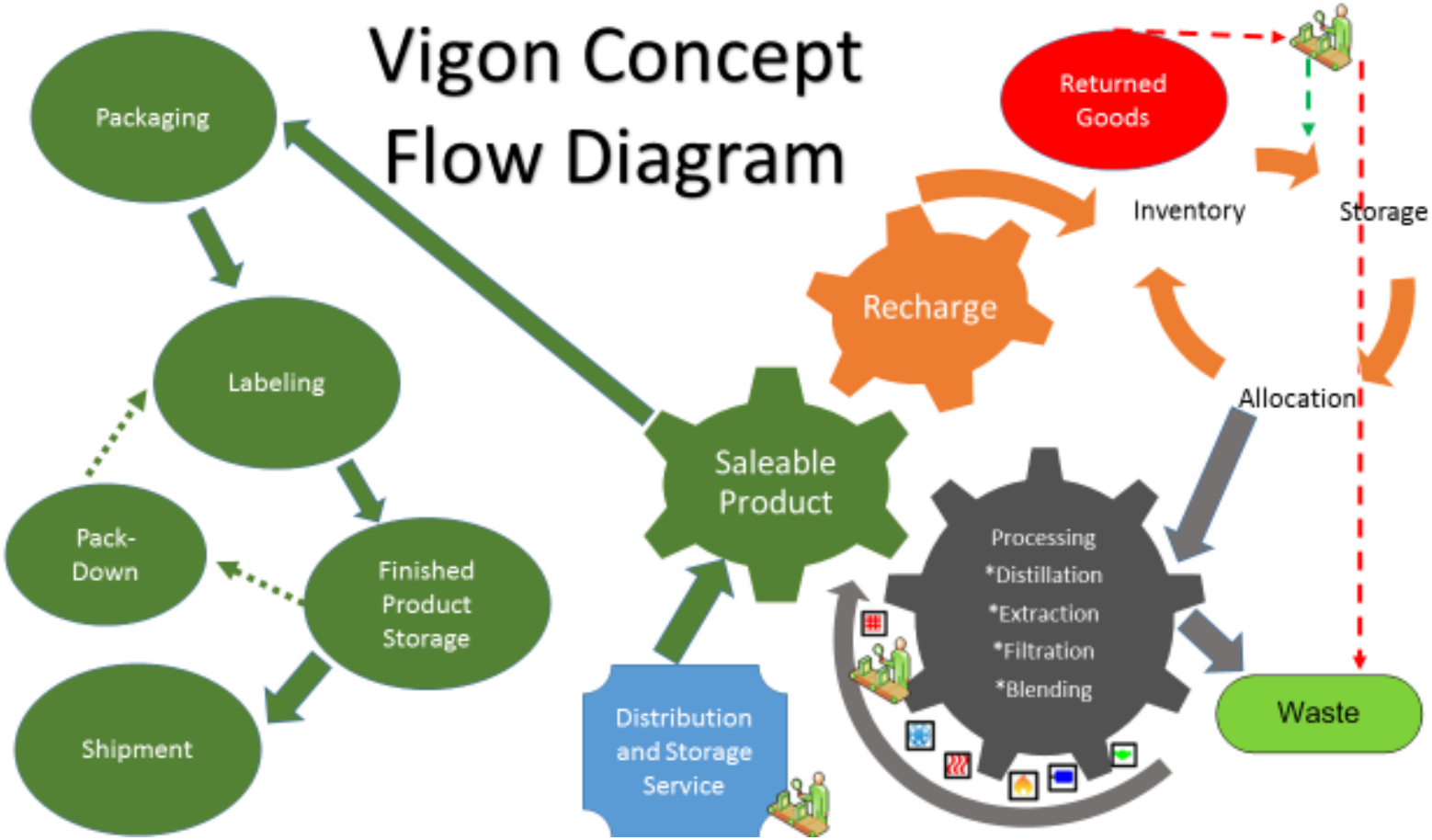
Verification: Internal Yearly Audit, Monthly VIR Audit, Food Security Training, Yearly Food Security Assessments

Preventative Control Programs Master Plan (PCP)

PCP	Food Safety Hazards to be controlled	Control Limits	Monitoring (Who, What, How, When)	Records	Corrections & Corrective Actions	Verification	Sources or References
Allergen Swabbing Controls	Allergen Hazard Contamination	ALLERSNAP Negative (Green/Gray <3ug/100cm^2) to Positive (Purple >10ug/100 cm^2) after 30 minutes of time lapse. 10ppm Threshold as set by FDA. = 10,000ug/ 100cm^2.	**Who**- QC Tech or FS Team Leader **What**- Zone 1 Product Contact **How**- 3cm x 3cm random swab **When**- After Allergen WO	Tracegains Powder Swabbing Form. Jotform liquid swabbing form, Cleaning Records in WO or QA Offices.	Re-clean and Re-swab. Quarterly Trending for Swabbing	Swabbing reports Quarterly Trending Report. Training for Hygiena Swabbing	Food Allergen Partnership (FDA Guidance Docs)
ENV Micro-biology Control	Pathogens (Salmonella and Listeria)	Charm Peel Plates Negative <100 in Z2 and <10000 in Zone 3. CAPA for anything over 10,000 and pathogen send out for Salmonella and Listeria. Yearly Pathogen Swabs send out	**Who**- QC Tech or FS Team Leader **What**- Zone 2,3,4 Environments **How**- 3cm x 3cm random swab **When**- Random Swabs	ENV Sampling Plan Folder and Results Trending Reports	Re-clean and Re-swab. Vector swabbing if + result. Follow up during next 3 weeks	Quarterly ENV Trending Reports	Environmental Monitoring Plan and Cleaning
Sanitation Swabbing Controls	Microbiological Hazard Contamination	ATP Hygiena ENSURE Negative < 0RLU to <50 RLU. As set by ENSURE Monitor and SUPERSNAP Test Swab	**Who**- QC Tech or FS Team Leader **What**- Zone 1 Product Contact **How**- 3cm x 3cm random area **When**- After Allergen WO	22-06F1 Swabbing Form. Cleaning Records in WO or QA Offices	Re-clean and Re-swab. Quarterly Trending for Swabbing	22-06F1, Quarterly Trending Report, Training for Hygiena Swabbing	Hygiena Industry References (A Guide to ATP Hygiene Monitoring)
Supply Chain	Physical, Chemical, and Micro Hazards	Risk Assessment based on GFSI 3rd Party Audit, HACCP Plan, and Item Assessment. Vendor and Item Food Approval or Non Approval	**Who**- FS Team Leader or Item Doc Specialist **What**- Supplier or Item Status **How**- Tracegains Risk Assessment **When**- Every New Vendor and Item	Tracegains uploads, Customer Complaint Cases in Sugar.	CAPA logged in PRR Quest, Supplier or Item Changes in Tracegains	Customer Complaint Trending, Annual RM Management Meeting	FSMA Preventative Controls Supply Chain Clause

PCP	Food Safety Hazards to be controlled	Control Limits	Monitoring (Who, What, How, When)	Records	Corrections & Corrective Actions	Verification	Sources or References
Recall Plan	Loss of Traceability	100±1% Product Trace in 4 hours or less	**Who**- FS Team Leader **What**- Traceability Systems **How**- Random WO or Material in production **When**- 2x per year. 1 Forward, 1 Backward	President and FS Team Notification. CAPA Initiated.	President and FS Team Notification. CAPA Initiated.	U drive> FS Team Folder> **Internal Audits**>Mock Recalls	FSMA Preventative Control Recall Plan Clause.

Vigon Concept Flow Diagram



*Please note that all references to allergens as chemical hazards in each section refer to: Dairy, Tree nuts, Wheat/Gluten, Peanuts, Soy, Sesame, Celery, Sulfites, and Mustard. Since they are too numerous to list in each section they will be listed here once.

**Radionuclides are listed as not applicable. Vigon has no suppliers in areas of concern in the Unites States. These areas are New Mexico (Los Alamos), Washington (Hanford), and Utah (Dugway/Wendover). Internationally, Vigon has no suppliers near the site of the Chernobyl nuclear disaster. Vigon has one backup supplier in Tokyo Japan, which is 3 hours away from Fukushima. The supplier tests its water and the product has a low water content.

Product Profiles, Process Hazards, Codex Alimentarius

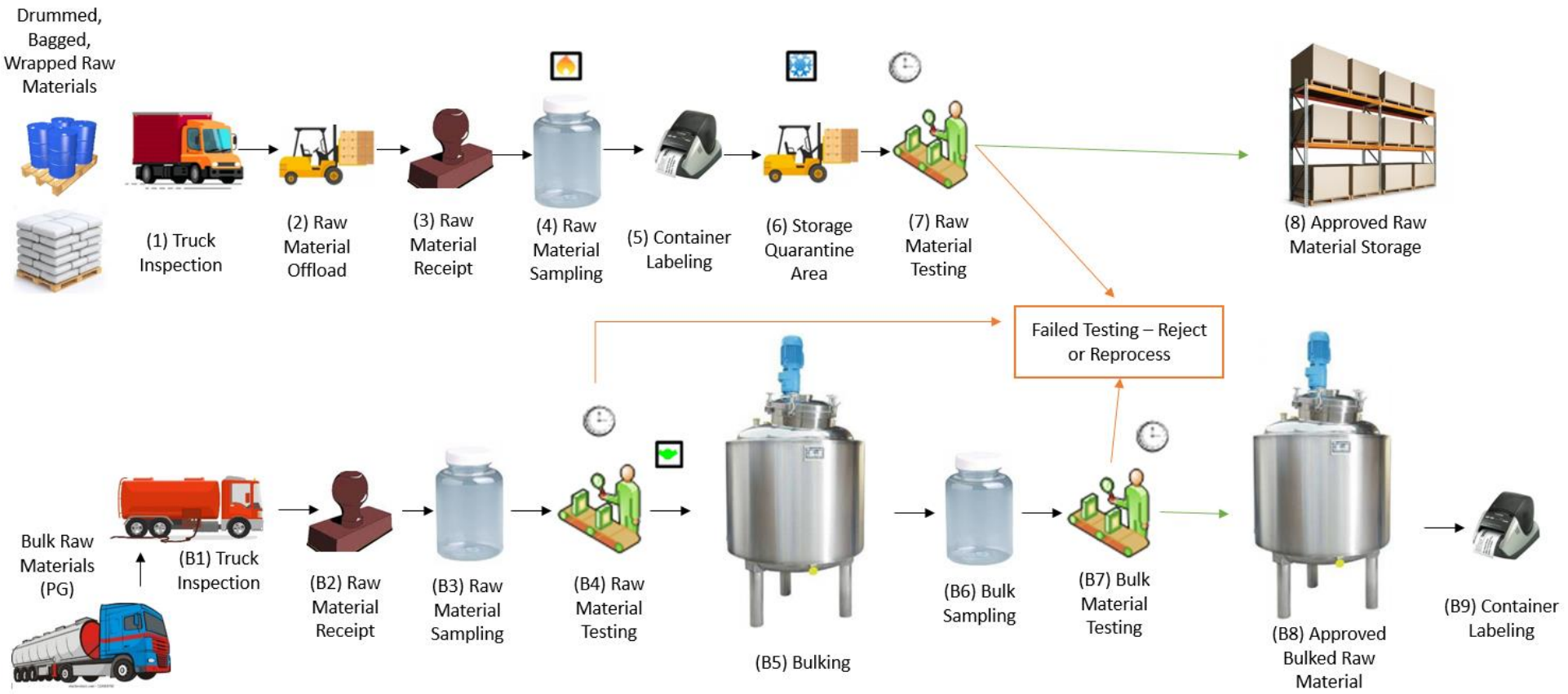
Receiving Product Profile

HACCP SCOPE: THE SCOPE OF THESE DOCUMENTS IS INTENDED TO SERVE AS A GUIDE IN THE MANUFACTURING OF REACTION AND DISTILLATION, COVERING ALL OF THE PROCESS STEPS FROM RECEIPT OF RAW INGREDIENTS TO THE SHIPPING OF FINISHED GOODS. THIS HACCP PLAN WAS DEVELOPED BY VIGON INTERNATIONAL'S FOOD SAFETY TEAM LISTED BELOW, IN ACCORDANCE WITH THE 7 PRINCIPLES ADOPTED BY THE CODEX ALIMENTARIUS COMMISSION, AND VERIFIED.

PRODUCT DESCRIPTION	
Product Category:	All Products (Liquid and Powder)
Process Description:	Flavor and Powder Finished Products
Intended use:	Concentrated flavor ingredient which may be used in flavor compounds according to legal and FEMA GRAS/FDA guidelines.
Raw Materials	Raw Materials are globally sourced and purchased only from approved suppliers. Raw materials are analyzed prior to receipt. This Raw Materials are Bulk and Non Bulk
Ingredients	Product Specific
Packaging	Plastic, Metal, Glass, Fibers, Tanker
Shelf Life/Storage	Product Specific at ambient temperature (46º-90°F)
Where will it be sold? Consumers? Intended Use?	Sold strictly as flavoring ingredients in food to manufacturers of consumer ready goods. All products are further processed prior to use by the general population.
Labeling	See Labeling procedures/work instructions
Transportation	Bulk and Non Bulk Transportation Controls

***ALL PROCESSED PRODUCTS IN THIS FACILITY ARE MARKETED GLOBALLY TO MANUFACTURERS WHO IN TURN FURTHER PROCESS THESE PRODUCTS TO/FOR THEIR CUSTOMERS/CONSUMERS. ALL RAW MATERIALS AND FINISHED PRODUCTS ARE IN COMPLIANCE UNDER THE FOOD, DRUG, AND COSMETIC ACT TITLE 21 CHAPTER 9 OF THE UNITED STATES CODE AND FOOD SAFETY MODERNIZATION ACT OF 2011.**

Raw Material Receipt



PROCESS HAZARD ANALYSIS

PROCESS STEP	KNOWN OR FORESEEABLE HAZARDS	LIKELIHOOD	SEVERITY	WHAT TYPE OF CONTROL DOES THIS REQUIRE?	HAZARD CONTROLLED BY	JUSTIFICATION/CONTROL MEASURES OR LATER PROCESSING STEPS
(1/B1)TRUCKING (TRUCK INSPECTION)	**P**: DIRT, TRUCK DAMAGE, PEST ACTIVITY, LEAKING/DAMAGED PRODUCT	C	4	GMP	VIGON	TRUCK INSPECTION
	B: MICRO ADULTERATION VIA DAMAGED PACKAGING OR TEMPERATURE ABUSE: B. CEREUS, S. AUREUS, SALMONELLA, C. PERFRINGENS, PEST MICROS	D	2	PRP	VIGON	TRUCK INSPECTION, TEMPERATURE LOGS
	C: CHEMICAL OR ALLERGEN SPILLAGE DURING TRANSIT, PRODUCT SHIPPED WITH INCOMPATIBLE PRODUCT	D	2	PRP	VIGON	TRUCK INSPECTION,
	R: N/A					
	EMA: N/A					
(2)RAW MATERIAL OFFLOAD	**P:** FORKLIFT PUNCTURES, PALLET PUNCTURES	C	4	PRP	VIGON	STORAGE POLICY, QC HOLD PROCEDURE, FORKLIFT TRAINING
	B: FORKLIFT PUNCTURE, CROSS CONTAMINATION WITH COLIFORM, BACILLALES	E	2	PRP	VIGON	STORAGE POLICY, HOUSEKEEPING, FORKLIFT TRAINING, LAB ANALYSIS OR DISCARD PRODUCT
	C: FORKLIFT PUNCTURE, CROSS CONTAMINATION WITH ALLERGENS OR LUBRICANTS	D	2	PRP	VIGON	STORAGE POLICY FOR ALLERGENS, HOUSEKEEPING. PRE INSPECTION OF RAW MATERIALS
	R: N/A					

	EMA: Vanilla, Mustard, oregano oil, turmeric, sage.	C	4	PRP	Vigon	Supplier Approval Program, Quality testing, COA, ISO seals
(3, B2) Raw Material Receipt (Scanning)	**P:** N/A					
	B: N/A					
	C: N/A					
	R: N/A					
	EMA: N/A					
(4, B3) Raw Material and Bulk Sampling	**P:** Cross Contam of Foreign Object during sampling (bung, pipette, dirty utensils, hair)	C	4	GMP	Vigon	Sampling Procedures, personnel hygiene policy
	B: Microbe Cross Contam from Gloves, skin, dirty utensils: Staph Aureus	D	2	PRP	Vigon	Hygiene Procedure, wash wear policy, personnel hygiene policy
	C: Cross Contam from Gloves or Equipment: Allergens or other chemicals	D	2	PRP	Vigon	Hygiene Procedure, GMP Procedure, Allergen Procedure
	R: N/A					
	EMA: N/A					
(5/B9)Container Labeling	**P:** N/A product sealed	E	4	PRP	VIGON	Pre/post equipment inspection
	B: N/A, container is sealed					
	C: Mislabeling (allergen, product)	C	3	PRP		Labeling procedure
	R: N/A					
	EMA: N/A					
(B5) Bulking. (Transferring from Bulk truck to Tanks)	**P:** Foreign Material from Bulk Transfer Hoses, FM from Truck. FM from Vigon Valve Lines: Metal or plastic	C	3	PRP	Vigon	Truck Inspection Procedure, Preventative Maintenance Procedure, Inline filtration
	B: Cross Contamination with Staph Aureus	D	2	PRP	Vigon	Personal Hygiene Procedure, PPE Procedure

	C: Cross contamination from previous bulk truck chemical, Wrong Product from Truck,	D	2	PRP	Vigon	Dedicated tankers, Truck Inspection, QC Testing Procedure. Hold Procedure
	R: N/A					
	EMA: N/A					
(6) Storage Quarantine	**P:** Drum liner degradation	C	4	PRP	Vigon	Storage policy, QC hold procedure,
	B: Cross contam with nonconform product	E	2	PRP	Vigon	Storage policy, Hold Procedure
	C: Cross contam with nonconform product	E	3	PRP	Vigon	Storage policy, Hold Procedure
	R: N/A					
	EMA: N/A					
(7/B4/B7) Raw Material (Bulking) Testing	**P:** Cross Contam of Foreign Object during sampling	D	4	GMP	Vigon	Sampling Policy
	B: Improper Sampling Technique: Staph Aureus, Improper Hold	D	2	GMP, PRP	Vigon	Lab sampling Procedures, Nonconformance and hold procedure
	C: Dirty sampling equipment	D	3	GMP, PRP	Vigon	Sampling procedure
	R: N/A					
	EMA: N/A					
(8/B8) Raw Material Storage	**P:** Foreign body introduction (drum liner degradation, drum puncture, holding tank sloughing)	C	4	GMP	Vigon	Storage policy, Pre-inspection of raw materials, QC testing, Filtration CCP step
	B: Environmental introduction of S. aureus, B. cereus, salmonella, listeria from drum puncture	E	2	PRP, GMP	Vigon	storage policy
	C: Allergen introduction from incorrectly stored products	E	3	PRP, PCP	Vigon	Allergen policy, Storage policy, pre-inspection of raw materials
	R: N/A					

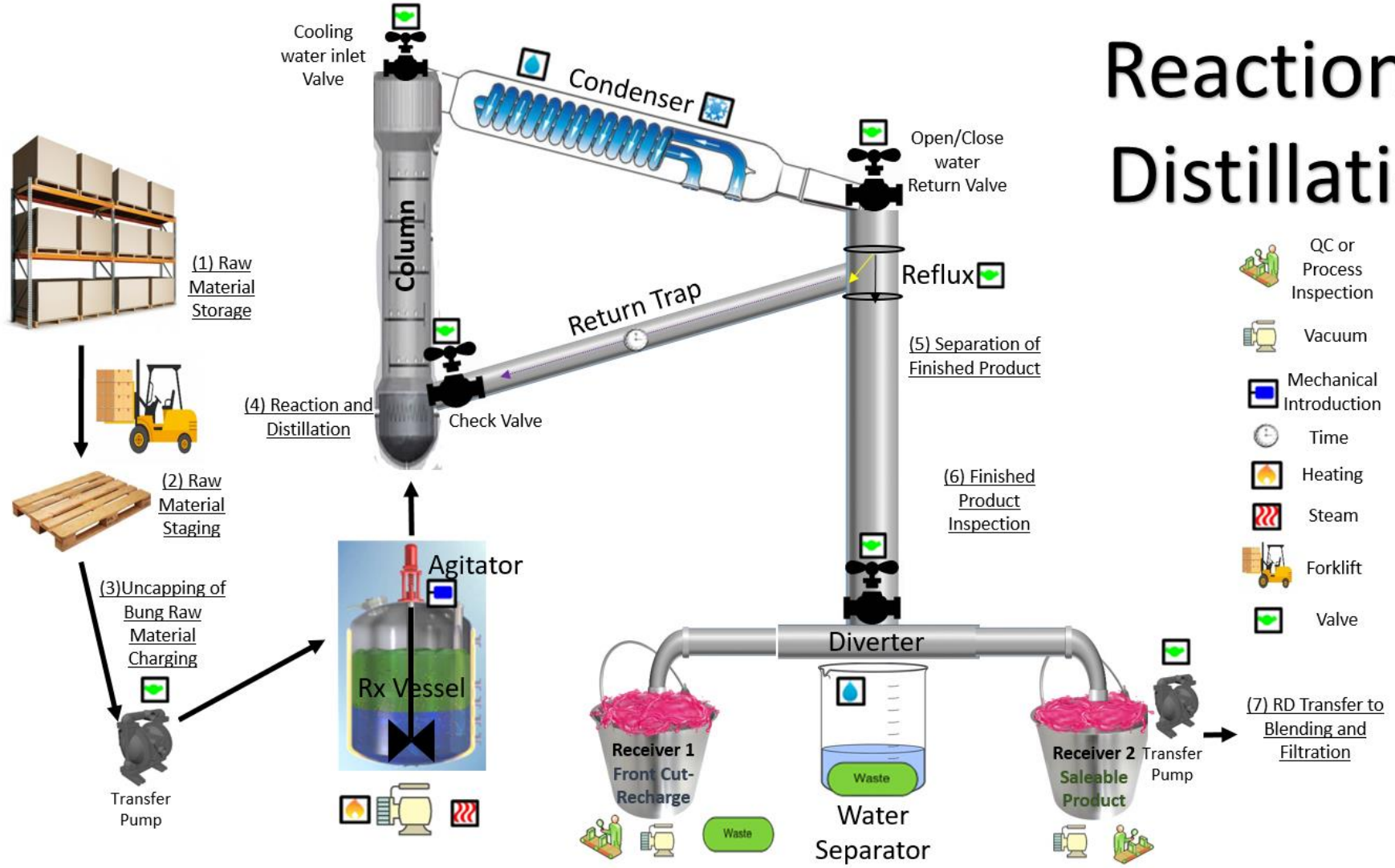
	EMA: N/A					

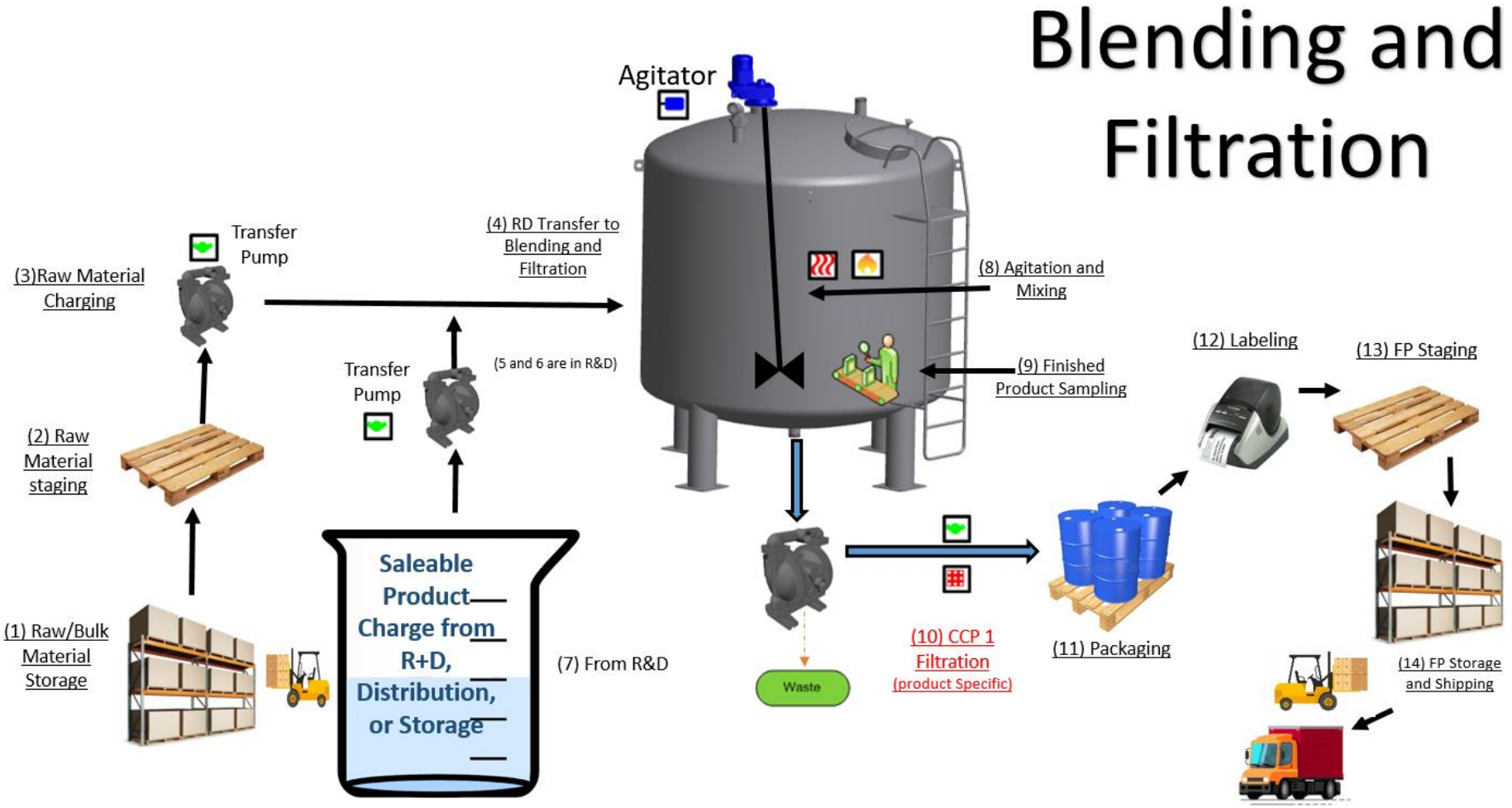
Reaction, Distillation, and Blending Product Profile

HACCP SCOPE: THE SCOPE OF THESE DOCUMENTS IS INTENDED TO SERVE AS A GUIDE IN THE MANUFACTURING OF REACTION/DISTILLATION AND BLENDING, COVERING ALL OF THE PROCESS STEPS FROM RECEIPT OF RAW INGREDIENTS TO THE SHIPPING OF FINISHED GOODS. THIS HACCP PLAN WAS DEVELOPED BY VIGON INTERNATIONAL'S FOOD SAFETY TEAM IN ACCORDANCE WITH THE 7 PRINCIPLES ADOPTED BY THE CODEX ALIMENTARIUS COMMISSION.

PRODUCT DESCRIPTION	
Product Category:	Flavor (Liquid) Ingredients
Process Description:	Flavor (Liquid) ingredients are ingredients which are added directly to other ingredients or derived through a chemical process to make a flavor.
Intended use:	Concentrated flavor ingredient which may be used in flavor compounds according to legal and FEMA GRAS/FDA guidelines.
Raw Materials	Raw Materials are globally sourced and purchased only from approved suppliers. Raw materials are sampled and analyzed prior to receipt.
Ingredients	Product Specific
Packaging	Plastic, Metal, glass
Shelf Life/Storage	Product Specific at ambient temperature (46º-90°F)
Where will it be sold? Consumers? Intended Use?	Sold strictly as flavoring ingredients in food to manufacturers of consumer ready goods. All products are further processed prior to use by the general population.
Labeling	See Labeling procedures/work instructions
Transportation	No special distribution control necessary

***ALL PROCESSED PRODUCTS IN THIS FACILITY ARE MARKETED GLOBALLY TO MANUFACTURERS WHO IN TURN FURTHER PROCESS THESE PRODUCTS TO/FOR THEIR CUSTOMERS/CONSUMERS. ALL RAW MATERIALS AND FINISHED PRODUCTS ARE IN COMPLIANCE UNDER THE FOOD, DRUG, AND COSMETIC ACT TITLE 21 CHAPTER 9 OF THE UNITED STATES CODE AND FOOD SAFETY MODERNIZATION ACT OF 2011.**


Reaction & Distillation
Cooling water inlet Valve
Condenser
Open/Close water Return Valve
Column
Reflux
Return Trap
(1) Raw Material Storage
(5) Separation of Finished Product
(4) Reaction and Distillation
Check Valve
(2) Raw Material Staging
(6) Finished Product Inspection
Agitator
(3)Uncapping of Bung Raw Material Charging
Rx Vessel
Diverter
Receiver 1 Front Cut-Recharge
Waste
Water Separator
Waste
Receiver 2 Saleable Product
Transfer Pump
(7) RD Transfer to Blending and Filtration
Transfer Pump
QC or Process Inspection
Vacuum
Mechanical Introduction
Time
Heating
Steam
Forklift
Valve


Blending and Filtration
Agitator
Transfer Pump
(3)Raw Material Charging
(4) RD Transfer to Blending and Filtration
(8) Agitation and Mixing
Transfer Pump
(5 and 6 are in R&D)
(9) Finished Product Sampling
(12) Labeling
(13) FP Staging
(2) Raw Material staging
Saleable Product Charge from R+D, Distribution, or Storage
(1) Raw/Bulk Material Storage
(7) From R&D
Waste
(10) CCP 1 Filtration
(product Specific)
(11) Packaging
(14) FP Storage and Shipping

PROCESS HAZARD ANALYSIS

PROCESS STEP	KNOWN OR FORESEEABLE HAZARDS	LIKELIHOOD	SEVERITY	WHAT TYPE OF CONTROL DOES THIS REQUIRE?	HAZARD CONTROLLED BY	JUSTIFICATION/CONTROL MEASURES OR LATER PROCESSING STEPS
(1)RAW MATERIAL STORAGE (DRUMS, {PLASTIC AND METAL)	**P:** DRUM LINER DEGRADATION	C	4	GMP	VIGON	STORAGE POLICY, FILTRATION LATER STEP
	B: MOST PRODUCTS NOT MICROSENSITIVE. STAPH AUREUS, SALMONELLA, E. COLI, ALICYCLOBACILLIS, LISTERIA INTRODUCTION FROM PACKING DAMAGE. B. CEREUS TEMPERATURE ABUSE ON PUREES, JUICES.	E	2	PRP	VIGON	STORAGE POLICY, HOUSEKEEPING, REFRIGERATOR POLICY
	C: ALLERGEN INTRODUCTION FROM OTHER STORAGE ITEMS AT WAREHOUSE. MYCOTOXINS (ASPERGILLUS, OCHRATOXIN) FROM INCORRECT STORAGE	D	2	PRP	VIGON	STORAGE POLICY FOR ALLERGENS AND NON-ALLERGENS, HOUSEKEEPING. PRE INSPECTION OF RAW MATERIALS
	R: N/A					
	EMA: N/A					
(2) RAW MATERIAL STAGING	**P:** FOREIGN MATERIAL INTRODUCTION FROM PUNCTURED DRUMS	E	4	GMP	VIGON	STORAGE POLICY, PRE INSPECTION OF RAW MATERIALS, FORKLIFT TRAINING
	B: STAPH AUREUS, SALMONELLA, E. COLI, ALICYCLOBACILLIS INTRODUCTION FROM PACKING DAMAGE. B. CEREUS TEMPERATURE ABUSE ON PUREES, JUICES.	E	2	PRP	VIGON	STORAGE POLICY, HOUSEKEEPING, REFRIGERATOR POLICY
	C: ALLERGENS INTRODUCTION FROM ENVIRONMENT	E	2	PRP	VIGON	STORAGE POLICY, HOUSEKEEPING

	R: N/A					
	EMA: N/A					
(3) RAW MATERIAL CHARGING (UNCAPPING OF BUNG AND PUMP SETUP)	**P:** TORQUE WRENCH (METAL FRAGMENTS), BUNG (EXCESS PLASTIC), ZIP TIES FROM BAGS	C	3	PRP/PCP	VIGON	FILTRATION OCCURS IN STEP 10
	B: DIRTY EQUIPMENT, PESTS/RODENT ACTIVITY, PERSONNEL HYGIENE ISSUES. STAPH AUREUS, SALMONELLA, E. COLI, ALICYCLOBACILLIS INTRODUCTION DURING CHARGING.	D	4	PRP	VIGON	PERSONNEL HYGIENE PROCEDURE, PRE/POST EQUIPMENT INSPECTION, QC TESTING FOR MICRO-SENSITIVE PRODUCTS, PEST CONTROL
	C: DIRTY EQUIPMENT HOSES, PUMP OIL, CLEANING CHEMICAL CONTAMINATION	D	3	PRP	VIGON	PRE/POST EQUIPMENT INSPECTION, ALLERGEN CONTROL PROGRAM. MAINTENANCE PROGRAM, CHEMICAL CONTROL PROGRAM
	R: N/A					
	EMA: N/A					
(4)REACTION AND DISTILLATION	**P:** FOREIGN MATERIAL FROM EQUIPMENT DEGREDATION, METAL TO METAL AGITATION	C	4	PRP	VIGON	PRE/POST EQUIPMENT INSPECTION, INGREDIENT INSPECTION, FILTRATION STEP 10
	B: DIRTY EQUIPMENT, PESTS/RODENT ACTIVITY, COOLING WATER CONTAMINATION	D	2	PRP	VIGON	PRE/POST EQUIPMENT INSPECTION, PEST CONTROL PROGRAM, PERSONNEL HYGIENE PROGRAM, MAINTENANCE PROGRAM
	C: CLEANING CHEMICAL CONTAMINATION, HEAVY METAL CONTAMINATION (CADMIUM, ARSENIC, LEAD, MERCURY)	C	3	PRP/PCP	VIGON	CLEANING VALIDATION PROGRAM, CLEANING SOPS MAINT. PROGRAM, FINISHED PRODUCT TESTING PROGRAM, PRE/POST INSPECTION
	R: N/A					
	EMA: N/A					
(5)SEPARATION OF PRODUCT	**P:** FOREIGN MATERIAL FROM ENVIRONMENT OR EQUIPMENT, SIGHT GLASS. PIPE INSULATION	D	4	PRP/PCP	VIGON	PRE/POST EQUIPMENT INSPECTION, BRITTLE PLASTIC AND GLASS PROCEDURE, MAINTENANCE PROGRAM

	B: STAPH AUREUS, SALMONELLA, E. COLI, LISTERIA INTRODUCTION FROM DIRTY / WET EQUIPMENT	D	4	PRP/PCP	VIGON	CLEANING VALIDATION PROGRAM PRE/POST EQUIPMENT INSPECTION, HYGIENE POLICY
	C: CLEANING CHEMICAL CONTAMINATION, IMPROPER CLEANING OF PREVIOUS PRODUCT; ALLERGEN CONTAMINATION FROM PREVIOUS PRODUCT	C	3	PRP/PCP	VIGON	CLEANING VALIDATION PROGRAM, CLEANING SOPS MAINT. PROGRAM, ALLERGEN PROCEDURE
	R: N/A					
	EMA: N/A					
(6) FINISHED PRODUCT TESTING (SAMPLING)	**P:** CROSS CONTAM OF FOREIGN OBJECT DURING SAMPLING	D	4	GMP	VIGON	SAMPLING POLICY
	B: STAPH AUREUS INTRODUCTION FROM POOR HYGIENE	D	4	GMP	VIGON	SAMPLING POLICY, HYGIENE POLICY
	C: ALLERGEN CROSS CONTAMINATION FROM DIRTY UTENSILS	E	3	GMP/PCP	VIGON	SAMPLING POLICY, ALLERGEN POLICY
	R: N/A					
	EMA: N/A					
(7)TRANSFER OF PRODUCT FROM RECEIVER TO BLENDING AND COMPOUNDING	**P:** FOREIGN MATERIAL FROM ENVIRONMENT OR EQUIPMENT (METAL, RUBBER GASKETS)	C	3	PRP/PCP	VIGON	PRE/POST EQUIPMENT INSPECTION, FILTRATION LATER STEP, MAINTENANCE PROGRAM
	B: STAPH AUREUS, SALMONELLA, LISTERIA INTRODUCTION DURING CHARGING FROM WET OR DIRTY EQUIPMENT	D	4	PRP/PCP	VIGON	PRE/POST EQUIPMENT INSPECTION, CLEANING VALIDATION, CLEANING SOP
	C: CLEANING CHEMICAL CONTAMINATION, IMPROPER CLEANING OF PREVIOUS PRODUCT	D	3	PCP	VIGON	CLEANING VALIDATION PROGRAM, CLEANING SOP
	R: N/A					
	EMA: N/A					

(8)AGITATION AND MIXING AT BLENDING AND COMPOUNDING	**P:** METAL TO METAL (AGITATOR), FOREIGN MATERIAL FROM OTHER EQUIPMENT SUCH AS RUBBER GASKETS	C	3	PRP/PCP	VIGON (LATER STEP)	PRE/POST EQUIPMENT INSPECTION, FILTRATION STEP 10, MAINTENANCE PROGRAM
	B: DIRTY / WET EQUIPMENT: SALMONELLA, LISTERIA, S. AUREUS, E. COLI	D	4	PRP/PCP	VIGON	CLEANING VALIDATION PROGRAM PRE/POST EQUIPMENT INSPECTION, CLEANING SOP
	C: ALLERGENS INTRODUCTION FROM EQUIPMENT OR ENVIRONMENT,	C	2	PCP	VIGON	ALLERGEN PROCEDURE/SWABBING, CLEANING AND SANITIZING PROGRAM, PRE/POST INSPECTION
	R: N/A					
	EMA: TURMERIC AND SAGE COLOR ENHANCEMENT. SUBSTITUTION OR DILUTION POSSIBLE ON HIGH COST ITEMS.	D	4	PRP		CCTV, BACKGROUND CHECKS ON EMPLOYEES, RFID SCAN CARDS, FINISHED PRODUCT LAB TESTING
(9) FINISHED PRODUCT SAMPLING	**P:** CROSS CONTAM OF FOREIGN OBJECT DURING SAMPLING	D	4	GMP/PCP	VIGON	SAMPLING POLICY, FILTRATION
	B: STAPH AUREUS INTRODUCTION	D	4	GMP	VIGON	SAMPLING POLICY, HYGIENE POLICY
	C: ALLERGEN CONTAMINATION FROM PREVIOUS UTENSILS	E	3	PRP/PCP	VIGON	SAMPLING PROGRAM, ALLERGEN PROCEDURE
	R: N/A					
	EMA: N/A					
(10) CCP 1 FILTRATION	**P:** FILTER DEGREDATION	C	4	PRP	VIGON	PRE AND POST EQUIPMENT INSPECTION, FOOD SAFETY EXCEPTION REPORT
	B: DIRTY EQUIPMENT: SALMONELLA, LISTERIA, E.COLI, STAPH AUREUS	C	4	PRP	VIGON	PRE/POST EQUIPMENT INSPECTION, DISHWASHING PROCEDURE,
	C: ALLERGENS INTRODUCTION FROM EQUIPMENT OR ENVIRONMENT,	C	2	PCP	VIGON	ALLERGEN PROCEDURE / SWABBING, CLEANING AND SANITIZING PROGRAM, CLEANING SOPS
	R: N/A					

	EMA: N/A					
(11)PACKAGING (INTO DRUMS/PAILS OR 1 GALLON JUGS BY A FILLER	**P:** FOREIGN MATERIAL FROM PACKAGING, INCORRECT STORAGE	D	4	GMP	VIGON	PRE/POST EQUIPMENT INSPECTION, STORAGE POLICY
	B: STAPH AUREUS, SALMONELLA, E. COLI INTRODUCTION FROM INCORRECT PACKAGING STORAGE OR EMPLOYEE HYGIENE	D	3	GMP/PRP	VIGON	PERSONNEL HYGIENE AND PRE/POST INSPECTION, STORAGE POLICY
	C: NON FOOD GRADE PACKAGING, CROSS CONTAMINATION	D	3	PRP	PACK. SUPPLIER	FOOD GRADE PACKAGING CERTS
	R: N/A					
	EMA: N/A					
(12)LABELING	**P:** N/A PRODUCT SEALED DURING LABELING					
	B: N/A PRODUCT SEALED DURING LABELING					
	C: MISLABEL OF ALLERGEN OR PRODUCT	C	3	PRP	VIGON	LABELING PROCEDURE
	R: N/A					
	EMA: N/A					
(13)FINISHED PRODUCT STAGING	**P:** N/A PRODUCT SEALED					
	B: N/A PRODUCT SEALED					
	C: N/A PRODUCT SEALED					
	R: N/A					
	EMA: N/A					
(14) FP STORAGE AND SHIPMENT	**P:** FOREIGN MATERIAL INTRODUCTION FROM DRUM LINER DEGRADATION	C	4	PRP	VIGON	STORAGE POLICY, SHELF POLICY
	B: PUNCTURED DRUM DURING STORAGE OR SHIPPING: INTRODUCTION OF E. COLI, STAPH AUREUS, SALMONELLA, LISTERIA	E	2	PRP	VIGON	STORAGE POLICY, TRUCK INSPECTION, FORKLIFT TRAINING, TRUCKING AGREEMENTS

	C: ALLERGENS INTRODUCTION FROM CONTAMINATED TRUCK OR INCORRECT STORAGE	E	3	PRP	VIGON	STORAGE POLICY, TRUCK INSPECTION, TRUCKING AGREEMENTS
	R: N/A					
	EMA: N/A					

CCP #1 – FILTRATION

CCP	Significant Hazard	Critical Limits	Monitoring				Records	Corrective Actions	Verification
			What	**How**	**Frequency**	**Who**			
Step 10 Filtration (Product Specific)	Physical: Foreign material >7mm and <25mm	Filtration is in place (product Specific). Filter is in good repair. Filter size used is as indicated on packaging report	Filter integrity and proper micron size	Visual inspection of filter on production packout report	During assembly of the filter housing (prior to startup) and at the end of each manufactured lot.	The operator will inspect the filter.	"Production Pack out Report" printout in Work Order. Food Safety Exception Report if any Findings are Found	If any of the critical limits are exceeded, operator shall inform their Supervisor and Quality Control. New filter will be installed as indicated on the packaging report. Product will be rerun over new filter.	Monthly VIR, Quarterly trending

Extraction Product Profile

HACCP SCOPE: THE SCOPE OF THESE DOCUMENTS IS INTENDED TO SERVE AS A GUIDE IN THE MANUFACTURING OF EXTRACTION LIQUIDS, COVERING ALL OF THE PROCESS STEPS FROM RECEIPT OF RAW INGREDIENTS TO THE SHIPPING OF FINISHED GOODS. THIS HACCP PLAN WAS DEVELOPED BY VIGON INTERNATIONAL'S FOOD SAFETY TEAM LISTED BELOW, IN ACCORDANCE WITH THE 7 PRINCIPLES ADOPTED BY THE CODEX ALIMENTARIUS COMMISSION, AND VERIFIED.

PRODUCT DESCRIPTION	
Product Category:	Flavor (Liquid) Ingredients
Process Description:	Extraction of botanical raw materials using a solvent
Intended use:	Human Consumption, Flavor ingredient
Raw Materials	Raw Materials are globally sourced and purchased only from approved suppliers. Raw materials are analyzed prior to receipt.
Ingredients	Product Specific
Packaging	Plastic totes/phenolic lined steel drums
Shelf Life/Storage	Product specific at ambient temperature (46º-90°F)
Where will it be sold? Consumers? Intended Use?	Sold strictly as flavoring ingredients in food to manufacturers of consumer ready goods. All products are further processed prior to use by the general population.
Labeling	See Labeling procedures/work instructions
Transportation	No special distribution control necessary

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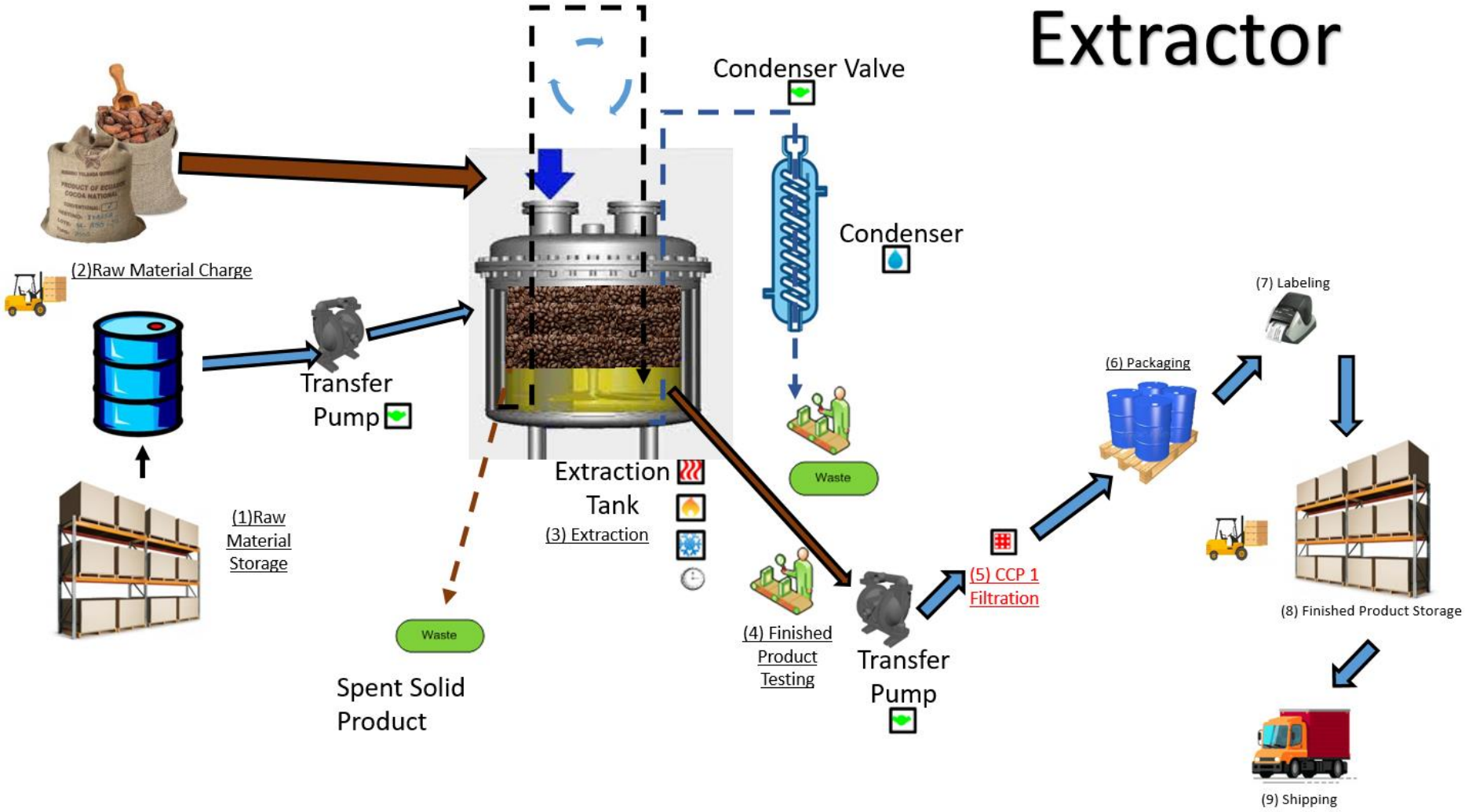
Extractor
Condenser Valve
Condenser
(2)Raw Material Charge
Transfer Pump
Extraction Tank
(3) Extraction
Waste
(1)Raw Material Storage
Waste
Spent Solid Product
(4) Finished Product Testing
Transfer Pump
(5) CCP 1 Filtration
(6) Packaging
(7) Labeling
(8) Finished Product Storage
(9) Shipping

PROCESS HAZARD ANALYSIS

PROCESS STEP	KNOWN OR FORESEEABLE HAZARDS	LIKELIHOOD	SEVERITY	WHAT TYPE OF CONTROL DOES THIS REQUIRE?	HAZARD CONTROLLED BY	JUSTIFICATION/CONTROL MEASURES OR LATER PROCESSING STEPS
(1)RAW MATERIAL STORAGE	**P:** DRUM LINER DEGRADATION	C	4	PRP	VIGON	STORAGE POLICY
	B: STAPH AUREUS, SALMONELLA, E. COLI, LISTERIA INTRODUCTION FROM RAW INCORRECT STORAGE	E	2	PRP	VIGON	STORAGE POLICY, HOUSEKEEPING, ENVIRONMENTAL POLICY
	C: MYCOTOXIN (OCHRATOXIN), ALLERGEN CONTAMINATION FROM SPILLS	E	2	PRP/PCP	VIGON	STORAGE POLICY, HOUSEKEEPING, ALLERGEN POLICY
	R: N/A					
	EMA: N/A					
(2)RAW MATERIAL CHARGE, TRANSFER TO EXTRACTION TANK	**P:** EXTRANEOUS NATURAL MATERIAL (TWIGS, STONES), FOREIGN MATERIAL FROM ENVIRONMENT OR EQUIPMENT (METAL, RUBBER, PLASTIC)	D	3	PRP	VIGON	PRE/POST EQUIPMENT INSPECTION, HOUSEKEEPING, MAINTENANCE PROGRAM, GLASS AND PLASTIC PROGRAM, FILTRATION LATER STEP
	B: SALMONELLA, LISTERIA, E. COLI, STAPH AUREUS INTRODUCTION FROM DIRTY EQUIPMENT, RAW MATERIAL OR EMPLOYEE. PEST CONTROL ISSUES	D	2	PRP/PCP	VIGON	PRE/POST EQUIPMENT INSPECTION, , ENV PROGRAM, PERSONNEL HYGIENE PROGRAM, PEST CONTROL, SUPPLIER APPROVAL
	C: ALLERGENS INTRODUCTION FROM EQUIPMENT OR ENVIRONMENT, PUMP OIL, CLEANING CHEMICAL CONTAMINATION	C	3	PCP	VIGON	ALLERGEN PROCEDURE/ SWABBING, CLEANING AND SANITIZING PROGRAM, CLEANING SOPS MAINT. PROGRAM
	R: N/A					
	EMA: SUBSTITUTION WITH TONKA BEANS IN PLACE OF VANILLA	D	7	PCP	VIGON	CCTV, BACKGROUND CHECKS, FINISHED PRODUCT QC TESTING

(3)EXTRACTION	**P:** EXTRANEOUS_ NATURAL MATERIAL (STONES OR TWIGS), METAL	A	2	CCP	VIGON (**LATER STEP**)	PRE/POST EQUIPMENT INSPECTION, FILTRATION LATER STEP
	B: NOT GENERALLY A CONCERN DUE TO SOLVENTS AND TEMPERATURES USED.					
	C: ALLERGENS INTRODUCTION FROM EQUIPMENT OR ENVIRONMENT, CLEANING CHEMICAL CONTAMINATION HEAVY METALS SUCH AS CADMIUM, LEAD, PESTICIDES	C	3	PCP	VIGON	ALLERGEN PROCEDURE / SWABBING, CLEANING AND SANITIZING PROGRAM, CLEANING SOPS MAINT. PROGRAM, QC TESTING AND COA
	R: N/A					
	EMA: N/A					
(4)FINISHED PRODUCT SAMPLING	**P:** CROSS CONTAMINATION OF FOREIGN OBJECT DURING SAMPLING (LOSS OF SAMPLING DEVICE)	D	4	GMP	VIGON	SAMPLING POLICY, FILTRATION
	B: CROSS CONTAMINATION OF STAPH AUREUS DURING SAMPLING	D	4	GMP	VIGON	SAMPLING POLICY, HYGIENE POLICY
	C: ALLERGEN CROSS CONTAMINATION (DIRTY EQUIPMENT)	E	3	PCP	VIGON	SAMPLING PROGRAM, ALLERGEN PROCEDURE
	R: N/A					
	EMA: N/A					
(5) CCP 1 FILTRATION	**P:** FILTER DEGREDATION	C	4	CCP	VIGON	PRE AND POST EQUIPMENT INSPECTION, FOOD SAFETY EXCEPTION REPORT
	B: SALMONELLA, STAPH AUREUS INTRODUCTION WITH DIRTY EQUIPMENT	C	4	PRP	VIGON	PRE/POST EQUIPMENT INSPECTION, HYGIENE PROGRAM, DISHWASHING PROCEDURE
	C: ALLERGENS INTRODUCTION FROM EQUIPMENT OR ENVIRONMENT	C	2	PCP	VIGON	ALLERGEN PROCEDURE / SWABBING, CLEANING AND SANITIZING PROGRAM, CLEANING SOPS
	R: N/A					
	EMA: N/A					

(6)PACKAGING	**P:** FOREIGN MATERIAL FROM PACKAGING DUE TO INCORRECT STORAGE	D	4	GMP	VIGON	PRE/POST EQUIPMENT INSPECTION, STORAGE POLICY
	B: STAPH AUREUS, SALMONELLA, E. COLI INTRODUCTION FROM INCORRECT PACKAGING STORAGE OR EMPLOYEE	D	3	PRP	VIGON	PERSONNEL HYGIENE AND PRE/POST INSPECTION, PACKAGING STORAGE
	C: NON FOOD GRADE PACKAGING, CROSS CONTAMINATION	D	3	PRP	PACK. SUPPLIER	FOOD GRADE PACKAGING CERTS
	R: N/A					
	EMA: N/A					
(7)LABELING	**P:** N/A PRODUCT SEALED DURING LABELING					
	B: N/A PRODUCT SEALED DURING LABELING					
	C: MISLABEL OF ALLERGEN OR PRODUCT	C	3	PRP	VIGON	LABELING PROCEDURE
	R: N/A					
	EMA: N/A					
(8) FINISHED PRODUCT STORAGE	**P:** FOREIGN MATERIAL INTRODUCTION FROM DRUM LINER DEGRADATION	C	4	PRP	VIGON	STORAGE POLICY
	B: PUNCTURED DRUM DURING STORAGE, INTRODUCTION OF E. COLI, STAPH AUREUS, SALMONELLA, LISTERIA	E	2	PRP	VIGON	STORAGE POLICY, FORKLIFT TRAINING
	C: ALLERGENS INTRODUCTION FROM INCORRECT STORAGE	E	3	PRP/PCP	VIGON	STORAGE POLICY, ALLERGEN POLICY
(9) SHIPMENT	**P**: N/A PRODUCT SEALED					
	B: N/A PRODUCT SEALED					

	C: ALLERGENS INTRODUCTION VIA INCORRECT STORAGE OR SPILLS DURING SHIPPING	E	3	PRP	VIGON	TRUCK INSPECTION AND AGREEMENTS
	R: N/A					
	EMA: POTENTIAL FOR THEFT, MISLABELING, DILUTIONS WHEN PRODUCT LEAVES FACILITY	C	4	PRP	VIGON	SHIPPING CONTAINERS ARE SEALED IN ISO17712 (TAMPER EVIDENT) SEALS

Codex Alimentarius

CCP #1 – FILTRATION

	Hazard	Limits	Monitoring				Records	Corrective Actions	Verification
			What	**How**	**Frequency**	**Who**			
Step Filtration	Physical: Foreign material >7mm and <25mm	Filtration is in place. Filter is in good repair. Filter size used is as indicated on packaging report	Filter integrity and proper micron size	Visual inspection of filter on the production pack-out report	During assembly of the filter housing (prior to startup) and at the end of each manufactured lot.	The operator will inspect the filter.	"Production Packout Report" printout in Work Order. Food Safety Exception Report if any Findings are Found	If any of the limits are exceeded, operator shall inform their Supervisor and Quality Control New filter will be installed as indicated on the packaging report. Product will be rerun over new filter.	Food Safety VIR and quarterly CCP trending

Powder Blends Product Profile

HACCP SCOPE: THE SCOPE OF THESE DOCUMENTS IS INTENDED TO SERVE AS A GUIDE IN THE MANUFACTURING OF POWDER BLENDS, COVERING ALL OF THE PROCESS STEPS FROM RECEIPT OF RAW INGREDIENTS TO THE SHIPPING OF FINISHED GOODS. THIS HACCP PLAN WAS DEVELOPED BY VIGON INTERNATIONAL'S FOOD SAFETY TEAM LISTED BELOW, IN ACCORDANCE WITH THE 7 PRINCIPLES ADOPTED BY THE CODEX ALIMENTARIUS COMMISSION, AND VERIFIED.

PRODUCT DESCRIPTION	
Product Category:	Powder Blends
Process Description:	**Plated Products**: Powders that have liquids (usually oils, fats, flavor compounds) added directly (plated) onto the component powder in a blender. **Powder Blends:** Powders (ingredients) that are added directly to other powders (ingredients) in a blender.
Intended Use:	Concentrated Flavor Ingredients
Raw Materials	Raw Materials are globally sourced and purchased only from approved suppliers. Raw materials are analyzed prior to receipt.
Ingredients	Product Specific
Packaging:	Plastic Bag, Cardboard container, Fiber drum
Shelf Life/Storage	Product Specific at ambient temperature (46°F-90°F)
Where will it be sold? Consumers? Intended Use?	Sold strictly as flavoring and ingredients in food to manufacturers of consumer ready goods. All products are further processed prior to use by the general population.
Labeling	See Labeling procedures/work instructions
Transportation	No special distribution control is necessary

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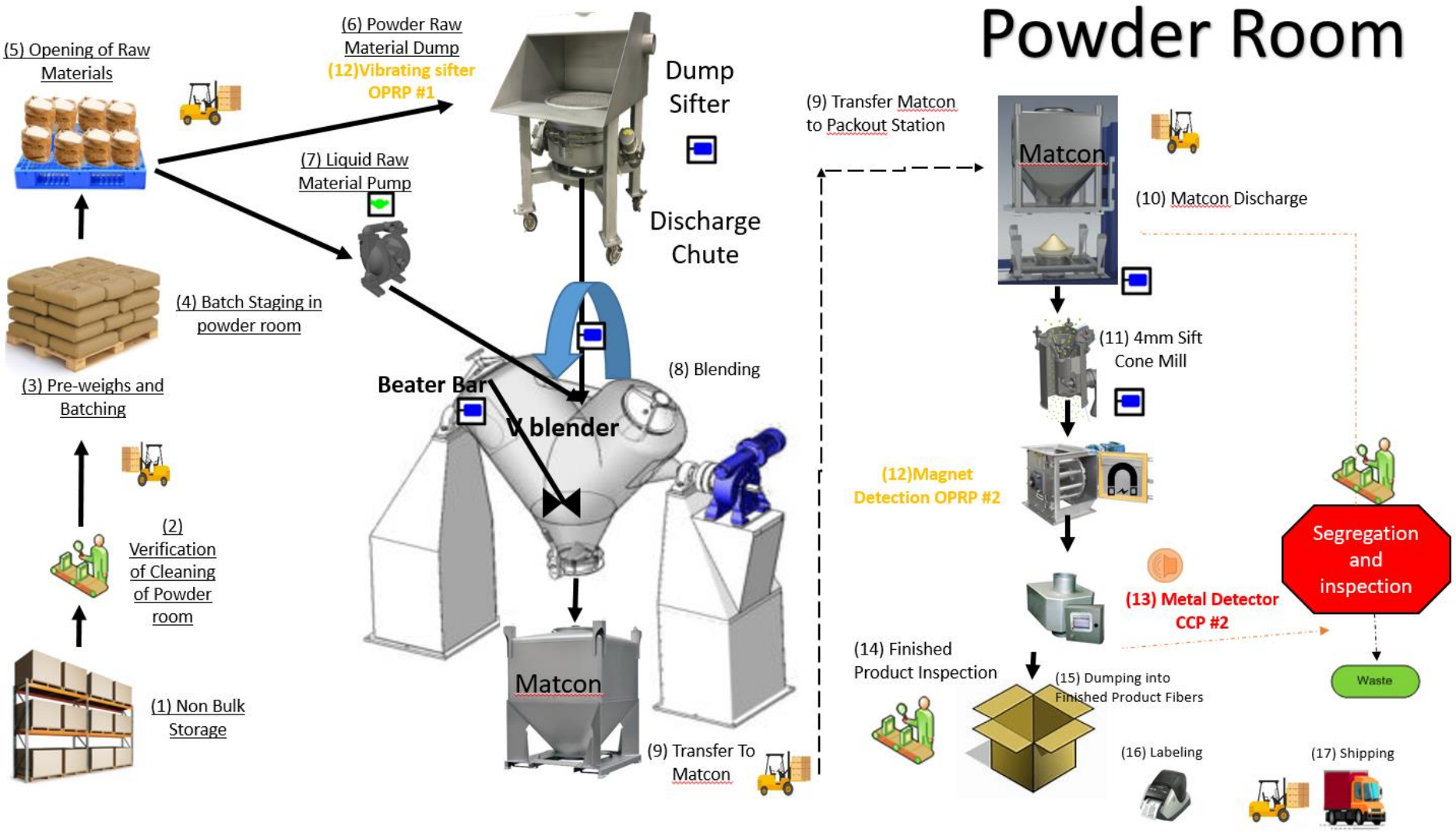
Powder Room
(5) Opening of Raw Materials
(6) Powder Raw Material Dump
(12)Vibrating sifter OPRP #1
Dump Sifter
(7) Liquid Raw Material Pump
Discharge Chute
(4) Batch Staging in powder room
(3) Pre-weighs and Batching
Beater Bar
V blender
(8) Blending
(2) Verification of Cleaning of Powder room
(1) Non Bulk Storage
Matcon
(9) Transfer To Matcon
(9) Transfer Matcon to Packout Station
Matcon
(10) Matcon Discharge
(11) 4mm Sift Cone Mill
(12)Magnet Detection OPRP #2
Segregation and inspection
(13) Metal Detector CCP #2
Waste
(14) Finished Product Inspection
(15) Dumping into Finished Product Fibers
(16) Labeling
(17) Shipping

PROCESS HAZARD ANALYSIS

PROCESS STEP	KNOWN OR FORESEEABLE HAZARDS	LIKELIHOOD	SEVERITY	WHAT TYPE OF CONTROL DOES THIS REQUIRE?	HAZARD CONTROLLED BY	JUSTIFICATION/CONTROL MEASURES OR LATER PROCESSING STEPS
(1)RAW MATERIAL STORAGE (50LB BAGS OF MATERIAL)	**P:** FOREIGN MATERIAL INTRODUCTION FROM STORAGE (PALLETS). PUNCTURES FROM WOOD AND FORKLIFTS	B	4	PRP	VIGON	STORAGE POLICY, DAMAGED MATERIAL PROCEDURE, FORKLIFT TRAINING
	B: STAPH AUREUS, SALMONELLA, E. COLI INTRODUCTION FROM BAG PUNCTURES	E	2	PRP	VIGON	STORAGE POLICY, DUAL SEALED PLASTIC IN FIBER DRUM OR ANOTHER BAG, DAMAGED MATERIAL PROCEDURE, FORKLIFT TRAINING
	C: ALLERGEN INTRODUCTION. AFLATOXIN (ASPERGILLUS, OCHRATOXIN, FUMONISNS, DEOXYNIVALENOL GROWTH FROM INCORRECT STORAGE	E	2	PRP/PCP	VIGON	STORAGE POLICY, HOUSEKEEPING, ALLERGEN PROCEDURE
	R: N/A					
	EMA: RECEIVED PRODUCTS TAINT OUR PRODUCTS (NATURAL VANILLIN) MADE WITH SYNTHETIC VANILLIN, WHEY POWDER CONTAMINATED WITH MELAMINE.	C	4	PRP/PCP	VIGON	SUPPLIER APPROVAL PROGRAM, GC TESTING
(2)CLEANING VERIFICATION (PCP)	**P:** EXTRA SWAB LEFT IN ZONE 1 AREA	D	4	GMP	VIGON	FOOD SAFETY TRAINING FOR SWAB TECH
	B: CROSS CONTAMINATION FROM SWABBING. STAPH AUREUS (IE. IMPROPER HAND SANITIZING AND GLOVE WEARING	E	3	GMP	VIGON	TRAINING OF SWABBING TECHS. HYGIENE AND GMP PROCEDURE
	C: EXCESS SOAP	D	2	PRP/PCP	VIGON	POWDER ROOM CLEANING PROCEDURE
	R: N/A					

	EMA: N/A					
(3) PREWEIGHS AND BATCHING	**P:** PLASTIC SCOOPS (PLASTIC FRAGMENTS), ZIPTIES USED FOR CLOSING BAGS, KNIVES TO CUT BAGS FOR PREWEIGHS (METAL FRAGMENTS)	C	4	PRP	VIGON	BRITTLE PLASTIC CONTROL, MONTHLY VIR INSPECTIONS, SIEVE ON DUMP SIFTER (OPRP)
	B: CROSS CONTAMINATION OF SALMONELLA, E. COLI, STAPH AUREUS	D	3	PCP	VIGON	ENVIRONMENTAL MONITORING AND VISUAL INSPECTION OF RAW MATERIALS
	C: ALLERGEN CONTAMINATION OR AFLATOXIN (ASPERGILLUS, OCHRATOXIN, FUMONISINS, DEOXYNIVALENOL) FROM MOLD GROWTH ON POWDER BAGS	D	2	PCP	VIGON	ALLERGEN PROCEDURE, STORAGE PROCEDURE
	R: N/A					
	EMA: N/A					
(4)BATCH STAGING IN POWDER ROOM	**P:** FOREIGN MATERIAL FROM ENVIRONMENT	D	3	PRP	VIGON	PRE/POST EQUIPMENT INSPECTION,
	B: MICROBIOLOGICAL INTRODUCTION, DIRTY EQUIPMENT, PESTS/RODENT ACTIVITY, HYGIENE (GLOVES): STAPH AUREUS, E. COLI, SALMONELLA, LISTERIA	D	2	PCP	VIGON	CLEANING AND SANITIZING PROGRAM PRE/POST EQUIPMENT INSPECTION, PEST CONTROL PROGRAM, ENV PROGRAM, PERSONNEL HYGIENE PROGRAM, WORKWEAR
	C: ALLERGENS INTRODUCTION FROM DIRTY EQUIPMENT OR ENVIRONMENT, PUMP OIL, CLEANING CHEMICAL CONTAMINATION	D	2	PCP	VIGON	ALLERGEN SWABBING, CLEANING AND SANITIZING PROGRAM, CLEANING SOPS MAINT. PROGRAM,
	R: N/A					
	EMA: N/A					
(5) OPENING OF RAW MATERIALS	**P:** FOREIGN MATERIAL FROM INGREDIENTS, PAPER FROM INGREDIENT BAGS, METAL FRAGMENTS, ZIP TIES	B	3	PRP	VIGON (LATER STEP)	FOOD SAFETY EXCEPTION FORM, SIEVE ON DUMP SIFTER, MAGNET / METAL DETECTION

	B: Microbiological Introduction from dirty employee, staph Aureus	D	2	GMP	Vigon	Personnel Hygiene Program
	C: Allergens Introduction from dirty equipment or Environment,	D	2	PRP/PCP	Vigon	Allergen Swabbing, Cleaning and Sanitizing Program, Cleaning SOPs
	R: N/A					
	EMA: N/A					
(6) Dump Station Sifter (vibrates) (OPRP 1)	**P.** Foreign Material From Ingredients, paper from ingredient bags, zip ties, metal	B	2	OPRP	Vigon	Pre and Post Equipment Inspection, Food Safety Exception Report Sieve on dump sifter
	B: Micro Sensitive product left in hard to clean ridges causing contamination and growth of Listeria, salmonella, or other coliform, pest or rodent activity	C	2	PCP	Vigon	ATP Swabbing, Cleaning and Sanitizing Program, Cleaning SOPs, Pest Control
	C: Allergen Product left in hard to clean ridges	C	2	PCP	Vigon	Allergen Swabbing, Cleaning and Sanitizing Program, Cleaning SOPs
	R: N/A					
	EMA: N/A					
(7A+B**)** Liquid and Powder Material Pump	**P:** Foreign Material From Ingredients, Foreign Material during Uncapping or in Pump Line	D	3	PRP	VIgon (later step_	Food safety exception report Metal Detection, Magnet
	B: Microbiological Introduction Staph Aureus, Dirty Equipment, Unchanged Hose	D	2	PRP/PCP	Vigon	ATP Swabbing, Cleaning and Sanitizing Program Pre/Post Equipment Inspection, hygiene policy,
	C: Allergen Contamination from unchanged hose	D	2	PCP	Vigon	Allergen Swabbing, Cleaning and Sanitizing Program, Cleaning SOPs

	R: N/A					
	EMA: N/A					
(8)BLENDING	**P:** METAL TO METAL FROM BEATER BAR	C	3	PRP	VIGON (LATER STEP)	PRE/POST EQUIPMENT INSPECTION, MAINTENANCE PROGRAM, FOOD SAFETY EXCEPTION REPORT, MAGNET / METAL DETECTOR
	B: _MICRO SENSITIVE PRODUCT LEFT IN HARD TO CLEAN RIDGES CAUSING CONTAMINATION_AND GROWTH OF LISTERIA, SALMONELLA, OR OTHER COLIFORM, PEST OR RODENT ACTIVITY	C	2	PCP	VIGON	ATP SWABBING, CLEANING AND SANITIZING PROGRAM PRE/POST EQUIPMENT INSPECTION, PEST CONTROL PROGRAM, ENV PROGRAM, PERSONNEL HYGIENE PROGRAM,
	C: ALLERGENS INTRODUCTION FROM EQUIPMENT OR ENVIRONMENT, CLEANING CHEMICAL CONTAMINATION	C	2	PCP	VIGON	ALLERGEN SWABBING, CLEANING AND SANITIZING PROGRAM, CLEANING SOPS
	R: N/A					
	EMA: N/A					
(9)TRANSFER TO MATCON	**P:** FOREIGN MATERIAL FROM ENVIRONMENT OR EQUIPMENT	D	3	PRP	VIGON	PRE/POST EQUIPMENT INSPECTION, MAGNET AND METAL DETECTION LATER STEP
	B: _MICRO INTRODUCTION FROM DIRTY EQUIPMENT: LISTERIA, SALMONELLA, PEST ACTIVITY: E. COLI, HYGIENE ISSUES: STAPH AUREUS	C	2	PCP	VIGON	ATP SWABBING, CLEANING AND SANITIZING PROGRAM PRE/POST EQUIPMENT INSPECTION, PEST CONTROL PROGRAM, ENV PROGRAM, PERSONNEL HYGIENE PROGRAM,
	C: ALLERGENS INTRODUCTION FROM EQUIPMENT OR ENVIRONMENT, CLEANING CHEMICAL CONTAMINATION	C	2	PCP	VIGON	ALLERGEN SWABBING, CLEANING AND SANITIZING PROGRAM, CLEANING SOPS
	R: N/A					
	EMA: N/A					
(10)MATCON DISCHARGE	**P:** METAL TO METAL AND LOOSE EQUIPMENT DROPPING INTO PACKAGING	B	2	PRP	VIGON (LATER STEP)	PRE AND POST EQUIPMENT INSPECTION, FOOD SAFETY EXCEPTION REPORT, MAGNET AND METAL DETECTOR LATER STEP

	B: MICRO INTRODUCTION FROM DIRTY EQUIPMENT: LISTERIA, SALMONELLA	C	2	PCP	VIGON	ATP SWABBING, CLEANING AND SANITIZING PROGRAM PRE/POST EQUIPMENT INSPECTION,
	C: ALLERGENS INTRODUCTION FROM EQUIPMENT OR ENVIRONMENT, CLEANING CHEMICAL CONTAMINATION	C	2	PCP	VIGON	ALLERGEN SWABBING, CLEANING AND SANITIZING PROGRAM, CLEANING SOPS
	R: N/A					
	EMA: N/A					
(11)CONE MILL	**P:** METAL TO METAL FRAGMENTS	C	4	PRP	VIGON	PRE AND POST EQUIPMENT INSPECTION, FOOD SAFETY EXCEPTION REPORT. MAINTENANCE PROGRAM, MAGNET AND METAL DETECTOR
	B: MICRO INTRODUCTION FROM DIRTY EQUIPMENT: LISTERIA, SALMONELLA	C	2	PCP	VIGON	ATP SWABBING, CLEANING AND SANITIZING PROGRAM PRE/POST EQUIPMENT INSPECTION,
	C: ALLERGENS INTRODUCTION FROM EQUIPMENT OR ENVIRONMENT, CLEANING CHEMICAL CONTAMINATION	C	2	PCP	VIGON	ALLERGEN SWABBING, CLEANING AND SANITIZING PROGRAM, CLEANING SOPS
	R: N/A					
	EMA: N/A					
(12)MAGNET (OPRP 2)	**P: METAL FRAGMENTS**			OPRP		MAGNET TO CATCH FRAGMENTS
	B: MICRO INTRODUCTION FROM DIRTY EQUIPMENT: SALMONELLA, LISTERIA	C	2	PCP	VIGON	ATP SWABBING, CLEANING AND SANITIZING PROGRAM PRE/POST EQUIPMENT INSPECTION, ENV PROGRAM
	C: ALLERGENS INTRODUCTION FROM EQUIPMENT OR ENVIRONMENT,	C	2	PCP	VIGON	ALLERGEN SWABBING, CLEANING AND SANITIZING PROGRAM, CLEANING SOPS
	R: N/A					
	EMA: N/A					
	P: METAL FRAGMENTS			CCP		METAL DETECTOR WILL ALARM IF METAL IS FOUND

(13) CCP 2 METAL DETECTOR	**B:** MICRO INTRODUCTION FROM DIRTY EQUIPMENT: SALMONELLA, LISTERIA	C	2	PCP	VIGON	ATP SWABBING, CLEANING AND SANITIZING PROGRAM PRE/POST EQUIPMENT INSPECTION, ENV PROGRAM
	C: ALLERGENS INTRODUCTION FROM EQUIPMENT OR ENVIRONMENT,	C	2	PCP	VIGON	ALLERGEN SWABBING, CLEANING AND SANITIZING PROGRAM, CLEANING SOPS
	R: N/A					
	EMA: N/A					
(14) FINISHED PRODUCT INSPECTION	**P:** CROSS CONTAMINATION OF FOREIGN OBJECT DURING SAMPLING,	D	4	GMP	VIGON	SAMPLING POLICY
	B: CROSS CONTAMINATION OF STAPH AUREUS DURING SAMPLING	D	4	GMP	VIGON	WORKWEAR POLICY, SAMPLING POLICY, HYGIENE POLICY
	C: NONFOOD GRADE PACKAGING	D	3	PRP	PACKAGING SUPPLIER	SAMPLING PROGRAM, LAB TESTING
	R: N/A					
	EMA: N/A					
(15) FINISHED PRODUCT PACKOUT	**P:** ZIP TIE FROM FINISHED PRODUCT PACKAGING	D	4	GMP	VIGON	PACKOUT TRAINING
	B: STAPH AUREUS FROM SEALING PRODUCT	D	4	GMP	VIGON	WORKWEAR POLICY, HYGIENE POLICY
	C: NONFOOD GRADE PACKAGING	D	3	PRP	PACKAGING SUPPLIER	SUPPLIER APPROVAL AND FOOD GRADE CERTS
	R: N/A					
	EMA: N/A					
FINISHED PRODUCT SHIPMENT	**P:** FORKLIFT PUNCTURE, INTRODUCTION OF FOREIGN PARTICLES	C	4	PRP	VIGON	STORAGE POLICY, FORKLIFT TRAINING
	B: FORKLIFT PUNCTURE: INTRODUCTION OF SALMONELLA, LISTERIA, STAPH AUREUS	E	2	PRP	VIGON	STORAGE POLICY, HOUSEKEEPING, FORKLIFT TRAINING, LAB TESTING OR DISPOSAL AFTER PUNCTURE

	C: ALLERGENS INTRODUCTION FROM IMPROPER STORAGE, FORKLIFT PUNCTURE, DIRTY TRUCK.	E	2	PRP/GMP	VIGON	STORAGE POLICY, HOUSEKEEPING, FORKLIFT TRAINING, TRUCK INSPECTION
	R: N/A					
	EMA: N/A					

OPERATIONAL PREREQUISITE CONTROL POINTS #1 MAGNETS

OPRP	Hazard	OPRP Limits	Monitoring				Records	Corrective Actions	Verification
			What	**How**	**Frequency**	**Who**			
Step **Dump Sifter Sieve OPRP 1**	Physical: Foreign material greater than	3 mesh, 7.087 mm	Sieve is clean, in good repair, and in place	Pre/post equipment inspection	Before and after every work order	Production specialist	Pre/post equipment inspection on work order print out	If any of the OPRP limits are exceeded, the Production Supervisor will immediately cease production and inform Quality Control to find source of material. Quarantine may be initiated	A review of all records will be performed on all work orders by Food Safety during cleaning verification. Trending
Magnet OPRP 2	Magnetic Foreign Material	Magnets are in place and clean. Magnets are tested by Pull strength Quarterly	Magnets are clean. Magnets still maintain Pull	Visual Inspection of Magnet Pull tested every 3 months	The magnet will be inspected prior to startup and at the end of each lot and every 3 months besides the annual calibration.	Production Specialist will inspect magnet Mx does pull test.	OPRP/(CCP) Monitoring Log (located on powder blend work orders) MX drive. Food Safety Exception Report	If any of the OPRP limits are exceeded, the Production Supervisor will immediately cease production and inform Quality Control Quarantine materials packed since last acceptable check.	A review of all records will be performed on all work orders by Food Safety during cleaning verification. Trending

								Suspect material will be reprocessed	

CRITICAL CONTROL POINT 2 –METAL DETECTION

CCP	Significant Hazard	Critical Limits	Monitoring				Records	Corrective Actions	Verification
			What	How	Frequency	Who			
Step CCP 2 Metal Detector	**Physical:** Metallic foreign material	Detector sensitivity: 1.0mm Fe/1.5mm Non-Fe/1.5mm Stainless Steel	Audible alarm at detection	Listening for alarm System will shut down with alarm and code is needed to reset	3x Coupon pre and post work order Audible Alarms during Work Order	Production Specialist	CCP Monitoring log (located on powder blend work orders) Food Safety Exception Report	If alarm sounds, cease production immediately and notify QC Quarantine materials packed since last acceptable check. Investigation to follow. If alarm does not sound during sample rod testing, contact Quality Control and Maintenance. Hold Back until last good check. SOP 22-18	Production Operator will record results on the CCP monitoring log. A review of all records will be performed on all work orders by Food Safety during cleaning verification. Trending reports

Homogenized Product Line

HACCP SCOPE: THE SCOPE OF THESE DOCUMENTS IS INTENDED TO SERVE AS A GUIDE IN THE MANUFACTURING OF HOMOGENIZED PRODUCTS, COVERING ALL OF THE PROCESS STEPS FROM RECEIPT OF RAW INGREDIENTS TO THE SHIPPING OF FINISHED GOODS. THIS HACCP PLAN WAS DEVELOPED BY VIGON INTERNATIONAL'S FOOD SAFETY TEAM IN ACCORDANCE WITH THE 7 PRINCIPLES ADOPTED BY THE CODEX ALIMENTARIUS COMMISSION.

PRODUCT DESCRIPTION	
Product Category:	Flavor (Liquid) and flavor dry Ingredients
Process Description:	Flavor (Liquid) ingredients are ingredients which are added directly to other ingredients or derived through a chemical process to make a flavor.
Intended use:	Concentrated flavor ingredient which may be used in flavor compounds according to legal and FEMA GRAS/FDA guidelines.
Raw Materials	Raw Materials are globally sourced and purchased only from approved suppliers. Raw materials are sampled and analyzed prior to receipt.
Ingredients	Product Specific
Packaging	Plastic, glass
Shelf Life/Storage	Product specific
Where will it be sold? Consumers? Intended Use?	Sold strictly as flavoring ingredients in food to manufacturers of consumer ready goods. All products are further processed prior to use by the general population.
Labeling	See Labeling procedures/work instructions
Transportation	Product specific

***ALL PROCESSED PRODUCTS IN THIS FACILITY ARE MARKETED GLOBALLY TO MANUFACTURERS WHO IN TURN FURTHER PROCESS THESE PRODUCTS TO/FOR THEIR CUSTOMERS/CONSUMERS. ALL RAW MATERIALS AND FINISHED PRODUCTS ARE IN COMPLIANCE UNDER THE FOOD, DRUG, AND COSMETIC ACT TITLE 21 CHAPTER 9 OF THE UNITED STATES CODE AND FOOD SAFETY MODERNIZATION ACT OF 2011.**


Agitator
(5) Homogenize product
(4) Transfer to Homogenizer
Transfer Pump
(3) Raw Material Charge
(5) CCP 1 Filtration
Feed
Seat
Impact ring
Homogenized product
Valve
(2) Raw Material Staging
(8) Packaging
(9) Labeling
(7) Finished Product Testing
(6) Post Homogenize Tanks
Pressurizing /Recharge Material
Finished Product Tank
(10) Finished Product Storage
(11) Shipping
(1) Raw Material Storage

PROCESS HAZARD ANALYSIS

PROCESS STEP	KNOWN OR FORESEEABLE HAZARDS	LIKELIHOOD	SEVERITY	WHAT TYPE OF CONTROL DOES THIS REQUIRE?	HAZARD CONTROLLED BY	JUSTIFICATION/CONTROL MEASURES OR LATER PROCESSING STEPS
(1) RAW MATERIAL STORAGE	**P:** FOREIGN MATERIAL INTRODUCTION FROM DRUM LINER DEGRADATION,	E	4	GMP	VIGON	STORAGE POLICY
	B: TEMPERATURE ABUSE OR MICROBE INTRODUCTION-LACTIC ACID BACTERIA, S. AUREUS, E. COLI, SALMONELLA OSMOPHILIC YEASTS, ALICYCLOBACILLUS, PASTEURIZATION DEVIATION FROM MANUFACTURER	D	2	PRP	VIGON	STORAGE POLICY, REFRIGERATION MONITORING, HYGIENE POLICY, SUPPLIER APPROVAL
	C: ALLERGEN CONTAMINATION FROM SPILLS-IMPROPERLY SEALED DRUMS, MYCOTOXINS FROM MANUFACTURER OR INCORRECT STORAGE (OCHRATOXIN, AFLATOXIN)	E	2	PRP/PCP	VIGON	STORAGE POLICY, HOUSEKEEPING, ALLERGEN POLICY, SUPPLIER APPROVAL PROGRAM
	R: N/A					
	EMA: DILUTION OR SUBSTITUTION BEFORE ARRIVAL OF HIGH VALUE JUICES WITH LOWER COST ONES	B	14	PCP	VIGON	GC TESTING, SUPPLIER APPROVAL PROGRAM
(2) RAW MATERIAL STAGING	**P:** FOREIGN MATERIAL INTRODUCTION FROM ENVIRONMENT, WOOD	E	4	GMP	VIGON	STORAGE POLICY
	B TEMPERATURE ABUSE OR MICROBE INTRODUCTION-LACTIC ACID BACTERIA,	E	2	PRP	VIGON	STORAGE POLICY, REFRIGERATION POLICY, HYGIENE POLICY

	S. AUREUS, E. COLI, SALMONELLA OSMOPHILIC YEASTS, B CEREUS ALICYCLOBACILLUS, HEAT RESISTANT MOLDS (TOO NUMEROUS TO LIST)					
	C: ALLERGEN INTRODUCTION FROM ENVIRONMENT OR MYCOTOXINS FROM IMPROPER STORAGE	E	2	PRP	VIGON	STORAGE POLICY, ALLERGEN PROGRAM, SUPPLIER APPROVAL, QUALITY TESTING
	R: N/A					
	EMA: N/A					
(3) ADDING WET / DRY INGREDIENTS TO PRE-MIXING TANK	**P:** FOREIGN MATERIAL INTRODUCTION, WRENCH, BUNG, ZIPTIES	C	4	PRP		EMPLOYEE TRAINING, BRITTLE PLASTIC POLICY AND LOG
	B: S. AUREUS, SALMONELLA, E. COLI INTRODUCTION FROM POOR HYGIENE OR DIRTY EQUIPMENT, LISTERIA INTRODUCTION FROM ENVIRONMENT	D	4	GMP/PRP/PCP	VIGON	PRE/POST EQUIPMENT INSPECTION, PEST CONTROL PROGRAM, HYGIENE POLICY, CLEANING AND SANITIZING PROGRAM, ENVIRONMENTAL MONITORING PROGRAM
	C: DIRTY EQUIPMENT OR UTENSILS	D	3	PRP	VIGON	PRE/POST EQUIPMENT INSPECTION, ALLERGEN CONTROL PROGRAM
	R: N/A					
	EMA: N/A					
(4)TRANSFER TO HOMOGENIZER, CCP 1 FILTRATION	**P:** FILTER DEGRADATION, METAL FRAGMENTS, BLOCKAGE	C	4	CCP	VIGON	PRE/POST EQUIPMENT INSPECTION, FOOD SAFETY EXCEPTION REPORT LOW PRESSURE CUT OFF SWITCH SHUTS DOWN HOMOGENIZER IF FILTER IS BLOCKED
	B: DIRTY EQUIPMENT, BACTERIA HARBORAGE SITES FOR SALMONELLA, LISTERIA FROM IMPROPER AND WET CLEANING	C	4	PRP/PCP	VIGON	PRE/POST EQUIPMENT INSPECTION, CLEANING AND SANITIZING PROCEDURE
	C: ALLERGEN INTRODUCTION FROM IMPROPER CLEANING	C	2	PCP	VIGON	ALLERGEN SWABBING, CLEANING AND SANITIZING PROGRAM, CLEANING SOP,
	R: N/A					
	EMA: N/A					

(5)Homogenizing	**P:** Foreign Material- equipment degradation (rubber or metal degredation)	C	4	GMP	Vigon	Pre/Post Equipment Inspection Monthly Preventative Maintenance (internal inspection)
	B: Dirty Equipment, bacteria harborage sites for salmonella, listeria from improper and wet cleaning	C	4	PRP/PCP	Vigon	Pre/post equipment inspection, cleaning and sanitizing procedure
	C: Pump oil, cleaning chemical contamination, allergen contamination	C	3	PRP / PCP	Vigon	Cleaning SOP, Maint. program, cleaning and sanitizing program
	R: N/A					
	EMA: N/A					
(6) Post Homogenizer Tanks	**P:** Foreign Material- equipment degradation (rubber or metal degredation)	C	4	PRP/GMP	Vigon	Pre/Post Equipment inspection, Lab testing, preventive maintenance
	B: S. aureus or E. coli introduction from poor hygiene, salmonella or listeria from dirty equipment	D	4	PRP/PCP	Vigon	Pre/Post Equipment Inspection, Hygiene policy, cleaning and sanitizing program
	C: dirty equipment or utensils contaminated with allergens	D	3	PRP/PCP	Vigon	Pre/Post equipment inspection, allergen policy and swabbing
	R: N/A					
	EMA: N/A					
(7) Finished Product Sampling	**P:** Contamination of Foreign Object during sampling (pipette or scoop)	D	4	GMP	Vigon	Sampling Policy
	B: Contamination of S. aureus during sampling	D	4	GMP	Vigon	Workwear Policy, Sampling Policy, hygiene policy
	C: Contamination of sampling equipment with allergens	E	3	GMP	Vigon	Sampling Procedure

	R: N/A					
	EMA: N/A					
(8) PACKAGING (DRUMS/PAILS)	**P:** FOREIGN MATERIAL FROM PACKAGING DUE TO INCORRECT STORAGE	D	4	GMP	VIGON	PRE/POST EQUIPMENT INSPECTION
	B: INTRODUCTION OF S. AUREUS VIA POOR HYGIENE	D	3	PRP	VIGON	PERSONNEL HYGIENE POLICY
	C: NON FOOD GRADE PACKAGING, CROSS CONTAMINATION	D	3	PRP	PACK. SUPPLIER	FOOD GRADE LINER CERTS
	R: N/A					
	EMA: N/A					
(9) LABELING	**P:** N/A PRODUCT SEALED AT THIS POINT	E	4	PRP	VIGON	
	B: : N/A PRODUCT SEALED AT THIS POINT	E	3	PRP	VIGON	
	C: MISLABEL OF ALLERGEN OR PRODUCT	C	3	PCP	VIGON	LABELING PROCEDURE
	R: N/A					
	EMA: N/A					
(10) FINISHED PRODUCT STORAGE	**P:** N/A PRODUCT SEALED					
	B: TEMPERATURE ABUSE OR MICROBE INTRODUCTION FROM FORKLIFT PUNCTURE-LACTIC ACID BACTERIA, S. AUREUS OSMOPHILIC YEASTS, ALICYCLOBACILLUS, HEAT RESISTANT MOLDS (TOO NUMEROUS TO LIST)	C	2	PRP	VIGON	STORAGE POLICY, HOUSEKEEPING, FRIDGE MONITORING, FORKLIFT TRAINING, FORMULA MANAGEMENT

	C: ALLERGENS INTRODUCTION FROM INCORRECT STORAGE	E	2	PRP	VIGON	STORAGE POLICY, ALLERGEN PROCEDURE
	R: N/A					
	EMA: N/A					
(11) SHIPMENT	**P:** N/A PRODUCT SEALED					
	B: TEMPERATURE ABUSE OR PUNCTURES: INTRODUCTION OF E. COLI, STAPH AUREUS, SALMONELLA, LISTERIA, B. CEREUS	E	2	PRP	VIGON	TRUCKING AGREEMENTS AND INSPECTIONS
	C: ALLERGENS INTRODUCTION FROM CONTAMINATED TRUCK OR INCORRECT STORAGE	E	3	PRP	VIGON	TRUCK INSPECTIONS AND AGREEMENTS

CCP #1 – FILTRATION

OPRP	Hazard	Limits	Monitoring				Records	Corrective Actions	Verification
			What	**How**	**Frequency**	**Who**			
Step Filtration	Physical: Foreign material >7mm and <25mm	Filtration is in place. Filter is in good repair. Internal filter size 40 mesh	Filter integrity and filter in correct position	Visual inspection Low pressure cut off switch shuts down homogenizer if filter is blocked	During assembly of homogenizer	The operator will inspect the filter.	"Production Packout Report" printout in Work Order. Food Safety Exception Report if any Findings are Found	If any of the limits are exceeded, operator shall inform their Supervisor and Quality Control Filter will be cleaned and inspected Product will be rerun over new filter.	Monthly VIR Quarterly trending

Down Packing Product Profile

HACCP SCOPE: THE SCOPE OF THESE DOCUMENTS IS INTENDED TO SERVE AS A GUIDE IN THE MANUFACTURING OF REACTION AND DISTILLATION, COVERING ALL OF THE PROCESS STEPS FROM RECEIPT OF RAW INGREDIENTS TO THE SHIPPING OF FINISHED GOODS. THIS HACCP PLAN WAS DEVELOPED BY VIGON INTERNATIONAL'S FOOD SAFETY TEAM LISTED BELOW, IN ACCORDANCE WITH THE 7 PRINCIPLES ADOPTED BY THE CODEX ALIMENTARIUS COMMISSION, AND VERIFIED.

PRODUCT DESCRIPTION	
Product Category:	Flavor (Liquid) and Powder Finished Product
Process Description:	Flavor and Powder Finished Products are downpacked to appropriate size based on customer orders
Intended use:	Concentrated flavor ingredient which may be used in flavor compounds according to legal and FEMA GRAS/FDA guidelines.
Raw Materials	Raw Materials are globally sourced and purchased only from approved suppliers. Raw materials are analyzed prior to receipt.
Ingredients	Product Specific
Packaging	Plastic, Metal, glass, Fibers
Shelf Life/Storage	Product Specific at ambient temperature (46º-90°F)
Where will it be sold? Consumers? Intended Use?	Sold strictly as flavoring ingredients in food to manufacturers of consumer ready goods. All products are further processed prior to use by the general population.
Labeling	See Labeling procedures/work instructions
Transportation	No special distribution control necessary

***ALL PROCESSED PRODUCTS IN THIS FACILITY ARE MARKETED GLOBALLY TO MANUFACTURERS WHO IN TURN FURTHER PROCESS THESE PRODUCTS TO/FOR THEIR CUSTOMERS/CONSUMERS. ALL RAW MATERIALS AND FINISHED PRODUCTS ARE IN COMPLIANCE UNDER THE FOOD, DRUG, AND COSMETIC ACT TITLE 21 CHAPTER 9 OF THE UNITED STATES CODE AND FOOD SAFETY MODERNIZATION ACT OF 2011.**

Down Packing

PROCESS HAZARD ANALYSIS

PROCESS STEP	KNOWN OR FORESEEABLE HAZARDS	LIKELIHOOD	SEVERITY	WHAT TYPE OF CONTROL DOES THIS REQUIRE?	HAZARD CONTROLLED BY	JUSTIFICATION/CONTROL MEASURES OR LATER PROCESSING STEPS
(1) STORAGE	**P:** DRUM OR BAG PUNCTURE: ENVIRONMENTAL DEBRIS, DRUM LINER DEGRADATION	C	4	PRP	VIGON	STORAGE POLICY, TRUCK INSPECTION, FORKLIFT TRAINING
	B: STAPH AUREUS, B. CEREUS, OR SALMONELLA INTRODUCTION FROM PUNCTURES OR TEMPERATURE ABUSE (MOST PRODUCTS ARE NOT MICROSENSITIVE, THIS ONLY APPLIES SO A FEW)	E	2	PRP	VIGON	STORAGE POLICY, TRUCK INSPECTION, FORKLIFT TRAINING, LAB TESTING OR DISPOSAL OF PRODUCT, REFRIGERATION POLICY
	C: ALLERGENS INTRODUCTION FROM INCORRECT STORAGE	E	3	PRP/PCP	VIGON	STORAGE POLICY, TRUCK INSPECTION, ALLERGEN POLICY
	R: N/A					
	EMA: N/A					
(2)FINISHED PRODUCT STAGING	**P:** DRUM LINER DEGRADATION	C	4	PRP	VIGON	STORAGE POLICY, SHELF LIFE POLICY
	B: N/A PRODUCT STILL SEALED					
	C: N/A PRODUCT STILL SEALED					
	R: N/A					
	EMA: N/A					
(3)UNCAPPING OR REMOVING LIDS	**P:** METAL TO METAL FROM BUNG, HAIR, PAPERBOARD SCRAPS, ZIPTIES	C	4	GMP	VIGON	HYGIENE POLICY, GLASS AND BRITTLE PLASTIC POLICY
	B: STAPH AUREUS INTRODUCTION FROM POOR HYGIENE	C	3	GMP	VIGON	HYGIENE POLICY
	C: ALLERGEN INTRODUCTION FROM SPILLAGE (INCORRECT STORAGE), OR DIRTY EQUIPMENT	D	2	PCP	VIGON	CLEANING AND SANITIZING PROCEDURE, ALLERGEN POLICY

	R: N/A					
	EMA: N/A					
(4)PRODUCT TRANSFER	**P:** DRUM LINER, HAIR, PAPERBOARD SCRAPS, ZIP TIES	C	4	PRP	VIGON	GLASS AND BRITTLE PLASTIC PROCEDURE, PACKOUT PROCEDURE
	B: STAPH AUREUS OR SALMONELLA INTRODUCTION FROM DIRTY EQUIPMENT OR POOR HYGIENE	C	3	GMP	VIGON	HOUSEKEEPING PROGRAM, HYGIENE POLICY, DISHWASHING
	C: ALLERGENS INTRODUCTION	D	2	PRP/PCP	VIGON	DISHWASHING TOOL AND UTENSILS, ALLERGEN TOOL SEGREGATION, ALLERGEN SWABBING
	R: N/A					
	EMA: N/A					
(CCP 1) FILTRATION OF PRODUCT (THIS STEP IS FOR KNOWN PRODUCTS WITH DRUM LINER DEGRADATION ISSUES)	**P:** CHEESECLOTH PARTICULATE FROM CUTTING	C	4	CCP	VIGON	PRE AND POST EQUIPMENT INSPECTION. FILTRATION FOR PRODUCTS THAT DEGRADE DRUM LINERS SUCH AS CITRUS.
	B: DIRTY EQUIPMENT: STAPH AUREUS OR E. COLI INTRODUCTION FROM POOR HYGIENE	C	4	GMP	VIGON	HYGIENE POLICY
	C: ALLERGEN INTRODUCTION FROM EQUIPMENT OR ENVIRONMENT	C	2	PCP	VIGON	ALLERGEN SWABBING, CLEANING AND SANITIZING PROGRAM, PRE/POST EQUIPMENT INSPECTION
	R: N/A					
	EMA: N/A					
(5)DOWN PACK	**P:** FOREIGN MATERIAL FROM INCORRECT PACKAGING STORAGE AND EMPLOYEE INTRODUCTION	D	4	GMP	VIGON	PRE/POST EQUIPMENT INSPECTION, WORKWEAR AND PERSONNEL HYGIENE POLICY, STORAGE POLICY
	B: STAPH AUREUS, SALMONELLA, E. COLI INTRODUCTION FROM INCORRECT	D	3	GMP/PRP	VIGON	PERSONNEL HYGIENE AND PRE/POST INSPECTION, PACKAGING STORAGE

	PACKAGING STORAGE OR EMPLOYEE CONTAMINATION					
	C: NON FOOD GRADE PACKAGING, CROSS CONTAMINATION	D	3	PRP	PACK. SUPPLIER	FOOD GRADE PACKAGING CERTS
	R: N/A					
	EMA: N/A					
(6)CAPPING AND SEALING	**P:** METAL TO METAL FROM BUNG	C	4	PRP	VIGON	PRE/POST EQUIPMENT INSPECTION
	B: STAPH AUREUS OR E. COLI INTRODUCTION, POOR HYGIENE	C	3	GMP	VIGON	HYGIENE POLICY
	C: ALLERGENS INTRODUCTION FROM INCORRECT CAP STORAGE	D	2	GMP	VIGON	STORAGE POLICY
	R: N/A					
	EMA: N/A					
(7)LABELING	**P:** N/A PRODUCT SEALED AT THIS POINT					
	B: N/A PRODUCT SEALED AT THIS POINT					
	C: MISLABEL OF ALLERGEN OR PRODUCT	C	3	PCP	VIGON	LABELING PROCEDURE
	R: N/A					
	EMA: N/A					
(8)DOWN PACK STAGING	**P:** FOREIGN MATERIAL INTRODUCTION FROM PUNCTURE OR DRUM LINER DEGRADATION	C	4	GMP	VIGON	STORAGE POLICY, SHELF LIFE POLICY, FORKLIFT TRAINING
	B: STAPH AUREUS OR SALMONELLA INTRODUCTION FROM PUNCTURE	E	2	GMP	VIGON	FORKLIFT TRAINING, LAB TESTING OR DISPOSAL FOR PUNCTURES
	C: ALLERGENS INTRODUCTION FROM IMPROPER STORAGE	E	2	PCP	VIGON	STORAGE POLICY, ALLERGEN PROCEDURE
	R: N/A					
	EMA: N/A					

(9)DOWN PACK STORAGE	**P:** DRUM LINER DEGRADATION	C	4	PRP	VIGON	STORAGE POLICY, SHELF LIFE POLICY
	B: N/A PRODUCT SEALED					
	C: ALLERGENS INTRODUCTION FROM INCORRECT STORAGE	E	3	PRP/PCP	VIGON	STORAGE POLICY, ALLERGEN PROCEDURE
	R: N/A					
	EMA: N/A					