Hazard Analysis and Critical Control Points Food Safety Plan

FDA GRAS Shelf Stable Dry Blend Process

5015 Manchester Ave.
St. Louis, MO 63110

SIGNED: Brian Kalkbrenner **DATE:** 11/28/2023

Operations Manager – Brian Kalkbrenner

II. Table of Contents

III. Change Log

Date of Change	What Changed	Reason for Changed
3/19/2021	NEW	New HACCP plan created from revision # 13 doc ID 5.0 of original HACCP plan (separated original HACCP plan into 4 individual HACCP plan to reflect unique processes), created new format, food safety team updated, added glossary of terms, updated facility overview, flow charts updated, ingredient hazard analysis updated, hazard analysis updated, master sheets updated
9/1/2021	Updated food safety team, updated flow chart and analysis to update to current plant practices, updated master sheet to include who is responsible for corrective/preventative actions, added decision making documents, added sanitation controls to hazard analysis	Internal audit identified gaps
10/3/2022	Updated the food safety team	
11/28/2023	Updated the food safety team, add glossary terms for mix off and rework, remove the biological hazards for mixing and sifting	Annual review

IV. Food Safety Team

Operations Manager	Brian Kalkbrenner^
Quality Manager	TBD
Warehouse Supervisor	Azmir Selmovic
Production Supervisor	TBD
Quality Technician	Matt Crabtree^

^ PCQI Certification Course

V. Glossary of Terms

Allergen Control Program	Systematic program for allergenic ingredients from receiving to processing to identify allergens introduced to product.
Approved Supplier Program	Program in place to approve vendors / suppliers for ingredients & packaging.
Biological	Hazards, including microbiological, such as parasites, environmental pathogens, and other pathogens.
Blending / Mixing:	Process step where ingredients according to formula are blended or mixed for further processing.
Bulk Storage:	Bulk ingredients stored in tanks / silo's until use
CCP Deviation:	Failure to meet a critical limit.
Chemical:	hazards, including radiological, such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens.
COA:	Term used for Certificate of Analysis
Cooling:	Process of bringing product down in temperature for further processing.
Corrective Action:	Procedures followed when a deviation occurs.
Preventative Control:	A point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.
Critical Limit:	A maximum or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.
Deviation:	Failure to meet standards or CCP requirements.
Distribution:	Term used for finished product shipments being distributed and sold frozen.
Dry Storage:	Term used for ingredients either boxed/bagged stored in warehouse until use
Established monitoring:	Procedure for recording temperatures (baked, frozen), pH's on appropriate audit sheets as outlined.
FDA:	Food and Drug Administration
Final Product Inspection:	Process which may include visual, analytical inspection prior to placement into final packaging.

Mix Off:	Material that remains from previous batches that was not enough for a full container
Food:	Food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.
Food Safety Hazard:	A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.
Foreign Object	Term used for any foreign object/material found that is not part of the process.
Freezer Storage:	Term used for storing finished product in finished goods freezer until shipment.
Freezing:	Process of freezing product to specified temperature before packaging.
Frozen Storage:	Term used for storing frozen ingredients in freezer until use.
GMP	Term used for Good Manufacturing Practices
HACCP Corrective Action Documentation Form:	Form used to document the procedure to be followed when a deviation occurs related to critical control point (s) that involves the failure to meet the critical limit.
HACCP:	A systematic approach to the identification, evaluation, and control of food safety hazards.
Hazard:	Any biological, chemical (including radiological), physical, or physical agent that is reasonably likely to cause illness or injury in humans or animals or humans in the absence of its control.
Hazard Analysis:	The section of the HACCP plan where biological, chemical and physical hazards are identified for each step in the production process and identifies how the hazards are to be prevented, eliminated or reduced to an acceptable level. At a minimum the following are considered: likely occurrence of hazard; severity of the effects on the consumer safety; vulnerability of those exposed, survival and multiplication of micro-organisms of concern; presence or production of toxins, chemicals or foreign bodies; contamination of raw materials, intermediate/semi-processed product or finished product; and potential for adulteration/deliberate contamination.
High Risk Supplier:	Suppliers of ingredients used post-lethality which have an inherent food safety risk associated with the ingredient. Ready-to-eat components which are fully processed and have no additional microbial interventions prior to assembly or application to finished product.

Monitor:	To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.
Packaging Storage:	Term used for packaging material stored in warehouse until use.
Packaging:	Process which may include: packaging, scaling, labeling, dating, and placement of the finished product into inner cartons, dome placement, lidding, or bagging prior to casing.
Prerequisite Programs:	Procedures, including Good manufacturing Practices that address operational conditions providing the foundation for the HACCP system.
Preventive Control:	Risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.
Process Deviation:	Failure to follow the established manufacturing process or process schedule and all the associated monitoring and verification activities required at each step of the process.
Reanalysis:	A review of the plant's Food Safety system for effectiveness and changes.
Receiving:	Process of bringing in a product or material which that plant will use to manufacture product.
Refrigerated Storage:	Term used for ingredients stored in coolers
Rework:	Term used to describe material is out of spec or returned and released by quality for use in the plant
RTE:	Abbreviation for Ready to Eat.
USDA	United States Department of Agriculture
SSOP	Term used for Standard Sanitation Operating Procedures
Validation:	That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.
Verification:	Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.

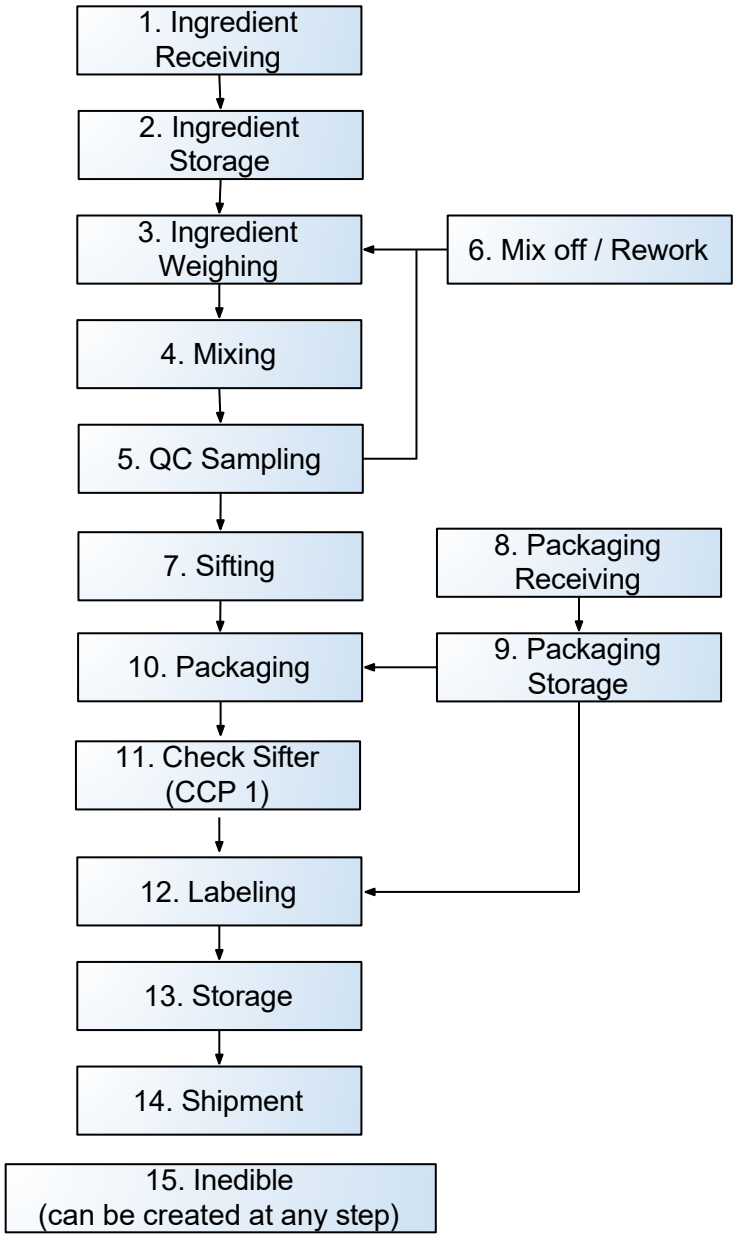
Water:	Potable water used in formulas.

VI. Facility Overview

Facility location:	St. Louis, MO
Product name:	Dry Blends
Product Description:	Dry blend of 2 or more ingredients
Product usage:	For edible product applications where further processing is carried out.
Packaging:	25 and 50 lb corrugated carton with PE plastic liner (zip-tied), or any other customer specified packaging
Storage temperature:	Prepared and stored at ambient temperature
Customer:	Manufacturers and producers of retail, food service, and industrial sales.
Labeling Instructions:	Store in cool dry place protected from light.
Distribution:	Shipped at ambient temperatures to customers in tamper proof containers.
Ultimate Consumers:	This product is intended to be eventually consumed by the general public, including children, elderly and immunocompromised after further processing into food; however, there are allergens present in certain products, including tree nuts, and soy. Allergy suffers shall read the individual product label specific allergy information.

Roha USA, LLC manufactures a wide variety of finished products with specific formulas. Variations of product color, raw material, solubility, etc. and packaging specifications expand the amount of item numbers. All finished product formulas, processing procedures and packaging requirements are available and easily accessible through a company-wide computerized system. All pertinent information contained in the finished product specifications is available to inspectors via the quality manager (or authorized designee) who has access. All information is considered confidential and proprietary trade secrets of Roha USA, LLC.

VII. Flow Chart **- Dry Blend Process**



Verified By: Brian Kalkbrenner

Date: 11/28/2023

IX. Hazard Analysis **– Dry Blend Process**

Ingredient, Processing Aid or Processing Step.	Reasonably Foreseeable physical, chemical & biological hazards introduced, controlled or enhanced at this step.	Is the reasonable foreseeable food safety hazard significant based on severity and probability?	Justification and/or basis for decision.	What control measures can be applied to prevent, eliminate or reduce the hazard(s) to an acceptable level?	Is this step a critical control point?
1. Ingredient Receiving	B – None C1 – Soy, Tree nuts C2 – Undeclared Allergens P – Foreign Material	B – No C – No P – No	B - Per Appendix 1 of the Hazard Analysis and Risk Based Preventive Controls for Human Food Draft Guidance, pathogens are not known to be present in these incoming ingredients. All incoming ingredients are Ready-to-Eat. Ingredients are received from an approved supplier and GMPs are in place to ensure proper storage of ingredients. C1 – Allergenic ingredients are known hazards in this product. C2 – There is an opportunity for the labels to be incorrect. P – Potential to receive foreign material from supplier	C1/C2 - All ingredients containing allergens will be properly labeled and segregated in storage per allergen control program P – Plant history does not indicate foreign material is a significant hazard.	No
2. Ingredient Storage	B – None C – Soy, Tree nuts P – None	C – No	B – The Food Safety Team could not identify any reasonably foreseeable biological hazards for this step. C – Allergenic ingredients are known hazards in this processing facility P – The Food Safety Team could not identify any reasonably foreseeable physical hazards for this step.	C – Allergen programs and GMPs are in place to ensure proper training, handling and processing of allergenic materials.	No
3. Ingredient Weighing	B – Listeria monocytogenes, Salmonella, APC C – None P – Gloves, Plastic, Corrugate	B – No P – No	B – In-plant monitoring of exposed environment for Listeria spp./salmonella through the environmental monitoring program has failed to identify a significant hazard for Listeria monocytogenes/salmonella. There is continuing data collection and on-going assessment of the hazard assessment. C – The Food Safety Team could not identify any reasonably foreseeable chemical hazards for this step. P – There is a potential for gloves to break off into the product. There is potential for plastic and corrugate from packaging to break off into the product	B – Environmental monitoring program in place. GMPs are in place to reduce the risk of biological contamination B – Sanitation controls are in place and verified via ATP swab. Master sanitation schedule in place. P – GMPs are in place. There is a subsequent filtering step	No

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4. Mixing	B – None C – Soy, Tree nuts P – Metal, Plastic, Gloves	C – No P – No	B – The Food Safety Team could not identify any reasonably foreseeable biological hazards for this step. C – Allergenic ingredients are known hazards in this processing facility. P - There is a potential for metal parts to break off into the product. There is a potential for gloves to break off into the product. There is potential for plastic from packaging to break off into the product	C – Allergen programs and GMPs are in place to ensure proper training, handling and processing of allergenic materials. P - GMPs are in place. There is a subsequent magnet/strainer/screen step	No
5. QC Sampling	B – None C – None P - Metal	P – No	B – The Food Safety Team could not identify any reasonably foreseeable biological hazards for this step. C – The Food Safety Team could not identify any reasonably foreseeable chemical hazards for this step. P – There is a potential for metal parts to break off into the product during sample pulling.	P - GMPs are in place. There is a subsequent magnet/strainer/screen step	No
6. Mix off / Rework	B – None C – Soy, Tree nuts P – Metal, Plastic, Gloves	C – No P – No	B – The Food Safety Team could not identify any reasonably foreseeable biological hazards for this step. C – Allergenic ingredients are known hazards in this processing facility. P – There is a potential for metal parts to break off into the product. There is a potential for gloves to break off into the product. There is potential for plastic from packaging to break off into the product	C – Allergen programs and GMPs are in place to ensure proper training, handling and processing of allergenic materials. P - GMPs are in place. There is a subsequent magnet/strainer/screen step	No

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7. Sifting	B – None C – None P – Metal, Plastic, Gloves	P – Yes	B – The Food Safety Team could not identify any reasonably foreseeable biological hazards for this step. C – The Food Safety Team could not identify any reasonably foreseeable chemical hazards for this step. P - There is a potential for metal parts to break off into the product. There is a potential for gloves to break off into the product. There is potential for plastic from packaging to break off into the product	P - GMPs are in place. Sifter step in place to catch foreign material that may have been introduced.	No
8. Packaging Receiving	B – None C – None P – None	No	B – The Food Safety Team could not identify any reasonably foreseeable biological hazards for this step. C – The Food Safety Team could not identify any reasonably foreseeable chemical hazards for this step. P – The Food Safety Team could not identify any reasonably foreseeable physical hazards for this step.		No
9. Packaging storage	B – None C – Soy, Tree nuts P – None	C – No	B – The Food Safety Team could not identify any reasonably foreseeable biological hazards for this step. C – Allergenic ingredients are known hazards in this processing facility P – The Food Safety Team could not identify any reasonably foreseeable physical hazards for this step.	C – Allergen programs and GMPs are in place to ensure proper training, handling and processing of allergenic materials.	No
10. Packaging	B – None C – None P – Gloves, Plastic, Metal	P – No	B – The Food Safety Team could not identify any reasonably foreseeable biological hazards for this step. C – The Food Safety Team could not identify any reasonably foreseeable chemical hazards for this step. P – There is potential for foreign material (torn gloves, pieces from pipes, etc.) to enter product during filling	P – Team members are trained on GMPs	No

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11. Check Sifter (CCP1)	B – None C – None P – Gloves, Plastic, Metal	P – Yes	B – The Food Safety Team could not identify any reasonably foreseeable biological hazards for this step. C – The Food Safety Team could not identify any reasonably foreseeable chemical hazards for this step. P - There is a potential for metal parts to break off into the product. There is a potential for gloves to break off into the product. There is potential for plastic from packaging to break off into the product	P - GMPs are in place. Filtering step in place to catch foreign material that may have been introduced	Yes
12. Labeling	B – None C – Undeclared allergens P – None	C – No	B – The Food Safety Team could not identify any reasonably foreseeable biological hazards for this step. C – There is potential for the label to not properly declare allergens (if present) P – The Food Safety Team could not identify any reasonably foreseeable physical hazards for this step.	C – Allergen control program in place, SAP system maintains label masters	No
13. Storage	B – None C – Soy, Tree nuts P – None	C – No	B – The Food Safety Team could not identify any reasonably foreseeable biological hazards for this step. C – Allergenic ingredients are known hazards in this processing facility P – The Food Safety Team could not identify any reasonably foreseeable physical hazards for this step.	C – Allergen programs and GMPs are in place to ensure proper training, handling and processing of allergenic materials.	No
14. Shipment	B – None C – None P – None	No	B – The Food Safety Team could not identify any reasonably foreseeable biological hazards for this step. C – The Food Safety Team could not identify any reasonably foreseeable chemical hazards for this step. P – The Food Safety Team could not identify any reasonably foreseeable physical hazards for this step.		No

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Ingredient, Processing Aid or Processing Step.	Reasonably Foreseeable physical, chemical & biological hazards introduced, controlled or enhanced at this step.	Is the reasonable foreseeable food safety hazard significant based on severity and probability?	Justification and/or basis for decision.	What control measures can be applied to prevent, eliminate or reduce the hazard(s) to an acceptable level?	Is this step a critical control point?
15. Inedible	B – None C – None P – None	No	B – The Food Safety Team could not identify any reasonably foreseeable biological hazards for this step. C – The Food Safety Team could not identify any reasonably foreseeable chemical hazards for this step. P – The Food Safety Team could not identify any reasonably foreseeable physical hazards for this step.		No

Reviewed and Approved by: _____
Date:

X. Critical Control Point Master Sheet **– Dry Blend Process**

Process Step	CCP Limits	Establishment Monitoring	Corrective Action	Records	System Verification
Check Sifter CCP 1	Sifting screen in place and Intact	What: sifting screen is in place and intact How: Visual inspection When: After each batch passes QC testing Where: Dry Processing Area Who: HACCP Trained Individual	**Actions taken when a CCP deviation occurs:** 1. Management is notified by production operators 2. Clean or replace sifter screen by production 3. Product is placed on hold by quality or entire batch is rerun with new sifter immediately by production **Corrective actions requirements:** 1. Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control; 2. Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur; 3. All affected product is evaluated for safety; and 4. All affected product is prevented from entering commerce.	1. Manufacturing Log Sheet 2. Hold Log 3. Hold Report	1. FSQA Management or HACCP trained individual will perform record review of each batch sheet 2. Quality team performs direct observation verification on liquids HACCP and/or dispersion, emulsion, viscous HACCP at least once daily if applicable 3. Reanalysis of entire HACCP plan will be performed at a minimum of annually or when an unforeseen hazard occurs.

XI. HACCP System Reassessment Checklist **– Dry Blend Process**

Types of Reassessments	▪ *Annual Reassessment* required by § 417.5(a) (3) will assess the adequacy of the HACCP program. Reassessment should be conducted whenever any changes occur that could affect the hazard analysis or alter the HACCP plan [such as, but not limited to, raw materials or source of raw materials, product formulation, slaughter or processing methods or systems, production volume, personnel, packaging, finished product distribution systems, intended use or consumers of finished product]. **Complete Section 1-3** ▪ *Initial Validation* required by § 304.3(c) during a period of not to exceed 90-days after the date the new product, or process, is produced for distribution in commerce, the establishment shall validate its HACCP plan, in accordance with § 417.4. **Complete Section 1-3** ▪ *Unforeseen Hazard Reassessment* § 417.3(b) will be conducted if a deviation not covered by specified corrective actions. **Complete Section 3 only**		
HACCP PROGRAM:	Dry Blend	CONDUCTED BY:	Brian Kalkbrenner
REASON FOR REASSESSMENT:	Annual reassessment and updated food safety team	DATE:	11/28/2023

TOPIC	YES	NO	IF "YES" DESCRIBE	ARE MODIFICATIONS TO THE HACCP PLAN OR HAZARD ANALYSIS REQUIRED?
1. EVALUATE PRODUCT & PROCESS				
Process Description Changed		X	Added mix off and rework to the glossary terms	
Any changes or additions on how is the product going to be used?		X		
Where will it be sold? [Intended use or consumers]		X		
Packaging materials or techniques changed or added?		X		
Any shelf-life changes or additions? Review HACCP shelf-life		X		
Any new labeling or distribution control methods changed or added?		X		
Any new suppliers?		X		
Any formulation changes or new ingredients added?		X		
Any new processing aides?		X		
Process flow diagram changes needed?		X		
Process changes, such chain speed, head killed or processed		X		
Equipment added or replaced or removed		X		
Personnel added or removed?	X		Additional members in food safety team	Yes, food safety team updated

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TOPIC	YES	NO	IF "YES" DESCRIBE	ARE MODIFICATIONS TO THE HACCP PLAN OR HAZARD ANALYSIS REQUIRED?
2. EVALUATE PRODUCT SAFETY HISTORY				
New potential hazard introduced, controlled or enhanced at a step		X		
New or emerging hazards reasonably likely to occur? Pathogens, etc.		X		
New control measures that can be applied to prevent the significance of a hazard?		X		
Excessive CCP deviations?		X		
Excessive critical limit deviations outside of the routine monitoring [non-programs]?		X		
Any occurrence of an unforeseen hazard?		X		
Failed performance standards? [Salmonella or Generic E. coli]		X		
Any industry recalls?		X		
Food safety consumer complaints		X		

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TOPIC	YES	NO	IF "NO" DESCRIBE	ARE MODIFICATIONS TO THE HACCP PLAN OR HAZARD ANALYSIS REQUIRED?
3. EVALUATE ADEQUACY OF CCPs, CRITICAL LIMITS, MONITORING, CORRECTIVE ACTION, CCP VERIFICATION, AND RECORD KEEPING PROCEDURES. REVIEW SUPPORTING PROGRAMS, HISTORICAL DATA AND SSOPs.				
Do the CCPs control the hazards?	X			
Are the CCP critical limits adequate?	X			
Do monitoring methods and frequency identify deviations?	X			
Do established corrective actions correct and control deviations?	X			
Do preventative measures prevent the reoccurrence of the deviations? Evaluate root causes, repetitive deviations.	X			
Are record keeping procedures adequate? Evaluate any deviations	X			
Records retention time period followed?	X			
Are verification activities of calibration processes adequate? Evaluate any deviations	X			
Are direct observation [shadowing or hands on] adequate? Evaluate any deviations	X			

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TOPIC	YES	NO	IF "NO" DESCRIBE	ARE MODIFICATIONS TO THE HACCP PLAN OR HAZARD ANALYSIS REQUIRED?
Do verification methods and frequencies adequate to identify deviations?	X			
Are the training procedures for monitors, verifiers, pre-shipment reviewers adequate? Evaluate training procedures and correlate them with any deviations	X			
Historical data support the process is under control? Temperatures, metal detection, etc.	X			
In-plant validations – Are control settings the same and still adequate as in the protocol?	X			
Can the HACCP team use the validations articles to support their CCPs and critical limits?	X			
Are pre-shipment review procedures adequate to prevent potentially adulterated product into commerce? Evaluate pre-shipment review deviations	X			

Appendix A – List of Supporting Documents

1) Food and Drug Administration Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry (August 2016)

2) Color Additives History, Food Safety Magazine, October/November 2013 issue, Julie N. Barrows, Ph. D, Arthur Lipman, Ph. D, Catherine J. Bailey, M. Ed.

XII. Additional Records **– Dry Blend Process**

Appendix B - Validation Worksheet and Decision Making Documents

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Dry Blend	Physical	Check sifter	In place and in tact	See appendix A for scientific references Prerequisite Programs: 5.5.1.15 Dry Blend Process SOP	In plant monitoring records for annual period recorded on batch log sheets