HACCP: **H**azard **A**nalysis and **C**ritical **C**ontrol **P**oints

A Food Safety Approach for Suppliers to the Food Industry

Packaging HACCP Plan Model: **Multiwall Bags**

Revision: 2-23-2012

Prepared by representatives of the following companies:

Berry Plastics
Campbell Soup Company
ConAgra Foods
Exopack, LLC
General Mills
Graham Packaging Company
Graphic Packaging
Kellogg
Nestle

Food Safety Alliance for Packaging **(FSAP)**
www.foodsafetyallianceforpackaging.com

This and all other FSAP HACCP Models are examples provided for guidance only. You need to assess your own requirements and risks before implementing any HACCP program.

HACCP Overview

1. What is HACCP?

HACCP (Hazard Analysis and Critical Control Points) is "a systematic approach to the identification, evaluation, and control of food safety hazards." It is an internationally recognized system used to identify and control Food Safety hazards. It is a preventative approach to Food Safety developed in the early 1970s by the Pillsbury Company and NASA.

2. Why is HACCP Needed for Packaging Suppliers?

Suppliers of Packaging to food producing companies are part of the food industry. Food Safety starts in the supply chain and continues through consumption. Packaging suppliers, especially those with direct product contact and/or printed materials, are important Food Safety partners.

3. What are the Packaging HACCP Models?

The Packaging HACCP Models are a series of publications designed to assist producers of food packaging with the implementation and installation of a HACCP program. They are designed to provide guidance in the development HACCP plans. The Packaging HACCP Models have been created by the Food Safety Alliance for Packaging (FSAP).

Food Safety Alliance for Packaging (FSAP) Initiative: The FSAP Initiative is a project involving major food producing companies, packaging companies, food industry associations, and consultants. The team's primary goal is to provide guidance to packaging companies with an emphasis on packaging-related Food Safety concerns. The FSAP strives to elevate Food Packaging Safety Awareness and provide resources for tools and training for the Packaging Supply Chain.

4. Who should use them?

The Packaging HACCP Models are intended to be used by companies supplying packaging components to food producers. They may be used by those packaging companies that are just beginning to implement HACCP and those wishing to evaluate their existing plan.

5. Applying this Model – What to Expect:

Upon reviewing this model and performing the applicable steps listed in section called ***Preparing a HACCP Plan*** *(starting on pg. 5)*, the facility will have implemented a basic HACCP program. The facility can expect to review existing documentation and create new documents. A small multi-disciplinary team will create the HACCP Plan and review and update it at least yearly. Upon following the steps and successfully completing the suggested documentation in this model, the facility's Food Safety program should be enhanced and meet the expectations of your customers.

6. Definitions

a. HACCP Plan: The written document which is based upon the principles of HACCP and which delineates the procedures to be followed.
b. Hazard: A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.
    i. Chemical: e.g., Cleaning Compounds, Allergens, Pesticides, etc.
    ii. Physical: e.g., Glass, Metal, Plastic, Wood, etc.
    iii. Microbiological: e.g., *Salmonella*, *Listeria*, *E. coli*, etc.

c. Hazard Analysis: The process of collecting and evaluating information on hazards associated with the packaging under consideration to decide which are significant and must be addressed in the HACCP plan. A list of hazards associated with raw materials and each process step is compiled. Each hazard will be evaluated when determining Critical Control Points. The HACCP Team must consider where the end product will be used. Product safety concerns are considered during the hazard analysis, not quality concerns.
d. CCP: Critical Control Point - A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.
e. CP: Control Point - Any step at which biological, chemical, or physical hazards can be controlled.
f. QCP: Quality Control Point - A step in the process where a quality parameter may be controlled.
g. PP or PRP: Prerequisite Programs – Existing Operating, Environmental, and support systems that allow the plant to produce safe products. Examples include, but are not limited to, Pest Control, Good Manufacturing Practices (GMP), and Preventive Maintenance.

7. Common Approach for HACCP Implementation

a. Assemble HACCP Team (multi-disciplinary)
b. Write Product Description (how is it made and what raw materials are used?)
c. Identify Target Audience (include markets and customers)
d. Create Process Flow Diagram
e. Verify Process Flow Diagram
f. Identify Hazards
g. Perform Hazard Analysis
h. Determine Critical Control Points (CCP)
    a. Use CCP Decision Tree
i. Establish Critical Control Point Limits (if applicable)
j. Establish Monitoring Procedures for Critical Control Points (if applicable)
k. Establish Corrective Actions for Critical Control Point Deviations (if applicable)
l. Verify HACCP Plan

8. Applying the Packaging HACCP Model – Multiwall Bags

The most common area for CCP's in the packaging industry is that of allergen issues due to mixed labels or materials. The following prerequisite programs must be in place to mitigate this potential issue:

a. **Design control** – each design must have a unique method for identification to ensure the ability to keep all plates, cylinders and other printing media separate to prevent the mixing of individual print media between production orders.
b. **Line Clearance** – the facility must have adequate procedures to ensure that all printed material, labels and containers are removed from machine centers prior to processing the next production run to prevent the mixing of materials.
c. **Finished roll, box and container control** – the facility must have adequate procedures to ensure the segregation of printed rolls, boxes and containers at each production step and rework areas to prevent the mixing of materials.
d. **Pallet Assembly and control** – the facility must have adequate procedures to ensure the segregation of pallets and associated packing labels to prevent the mixing of materials, labels or shipment of incorrect materials.

9. HACCP Training

a. HACCP Team Leader – It is recommended that this person has formal training from an accredited organization such as AIB or Silliker Labs. (*See FSAP website*)
b. HACCP Team Members – Team members should receive formal documented training from the team leader or person knowledgeable in HACCP.

c. Facility Employees – Should receive documented training upon hiring and at least yearly thereafter.
d. Those with CCP Monitoring Responsibility – Should receive documented training specific to the CCP they monitor in addition to annual plant-wide training.
e. Training Records – HACCP training must be documented and the records maintained per the facility's record retention policy.

10. Record Keeping & Documentation:

Records provide evidence that procedures are being followed and CCPs are monitored as required. They provide objective evidence to internal and external auditors. As in ISO 9000, if something is not documented, it's not done.

a. Types of documents plant will need: Examples are provided in the ***Preparing a HACCP Plan*** section of this model. In short, the plant documentation will include: the HACCP Plan; Hazard Analysis; HACCP Procedures; HACCP Records; a list of HACCP trained personnel and team members; and, supporting documentation from the Prerequisite Programs (*See FSAP website*).
b. Completing HACCP Records: HACCP records should be completed at the time of use. Information should be recorded in permanent ink.
c. Review of HACCP Records: CCP records should be reviewed by a trained company representative prior to releasing an order for shipment. The review must be documented.
d. Proper documentation practices: The plant should follow proper documentation practices such as prohibiting the use of correction fluid (white-out) and pencil on permanent records. Also, changes to entries should be made using a single line-out along with initialing and dating the change. A documentation practices procedure should be in place.
e. HACCP Record Retention: The plant's record retention policy should include a retention time for HACCP records. In many cases, this will be two years.

Preparing a HACCP Plan

Step 1: Assemble the HACCP Team

- Cross Functional Team
- Management Sponsorship / Buy-In / Participation
- HACCP Training
- Documents: Team List / Charter with Management Sign-Off / Facility Training Log

Facility HACCP Team			
Facility Name: Koyukuk Brands, Wiseman, AK		**Date**: November xx, 20xx	
Team Member Name	**Position**	**HACCP Team Role**	**Signature**
D. Stohn	Facility Manager	Member	D. Stohn
L. Middlekauf	Corporate Quality and CI	Advisor	L. Middlekauf
M. Starcke	Q.A./Product Safety/Env	Team Leader	M. Starcke
A. Ambrose	Converting Mgr.	Member	A. Ambrose
D. Nickola	Printing Supvsr	Member	D. Nickola
L. Tamblin	Converting – Lead Operator	Member	L. Tamblin
S. Reimold	Shipping/Receiving Coordinator	Member	S. Reimold
J. Graham	Printing Operator	Member	J. Graham
C. Edwards	Maintenance Technician	Member	C. Edwards

Facility HACCP Charter

Facility Name: Koyukuk Brands, Wiseman, AK	**Date**: November xx, 20xx

The purpose of the facility HACCP Team is to ensure safe products for our customers and their consumers. The HACCP Team will evaluate raw materials and processes to determine Critical Control Points. Critical Control Points will be monitored as will other points and processes. The team will provide documented training for the facility. The facility HACCP Plan will be re-assessed at least annually. Facility management will provide adequate resources for the implementation and maintenance of the HACCP Program.

Sign-off and Approval

Position:	**Name**:	**Signature**:
Position:	**Name**:	**Signature**:
Facility Manager	D. Stohn	D. Stohn
Corporate Quality & Continuous Improvement	L. Middlekauf	L. Middlekauf
Quality Assurance Manager	M. Starcke	M. Starcke
Converting Manager	A. Ambrose	A. Ambrose
Printing Supervisor	D. Nickola	D. Nickola
Lead Operator	L. Tamblin	L. Tamblin
Coordinator	S. Reimold	S. Reimold
Operator	J. Graham	J. Graham
Technician	C. Edwards	C. Edwards

Facility Training Log	Koyukuk Brands -- Wiseman, AK	
Subject:	***Food Safety and HACCP Introduction***	
Date(s):	***November 23, 20xx***	
Trainer's Name & Title:	***L. Middlekauf - Director of Quality & CI***	
Materials Used:	***Food Safety Introduction***	
Print Name:	**Signature**:	**Date**:
D. Stohn	D. Stohn	Jan. 14, 20XX
L. Middlekauf	L. Middlekauf	Jan. 14, 20XX
M. Starcke	M. Starcke	Jan. 14, 20XX
A. Ambrose	A. Ambrose	Jan. 14, 20XX
D. Nickola	D. Nickola	Jan. 14, 20XX
L. Tamblin	L. Tamblin	Jan. 14, 20XX
S. Reimold	S. Reimold	Jan. 14, 20XX
J. Graham	J. Graham	Jan. 14, 20XX
C. Edwards	C. Edwards	Jan. 14, 20XX

Preparing a HACCP Plan (continued)

Step 2: Write Product Description

a. What do you make
b. How do you make it
c. Intended usage (include time and temperature as applicable)
d. What Raw Materials are used
e. Intended markets / customers
f. Document: Written Descriptions of what is made and production process

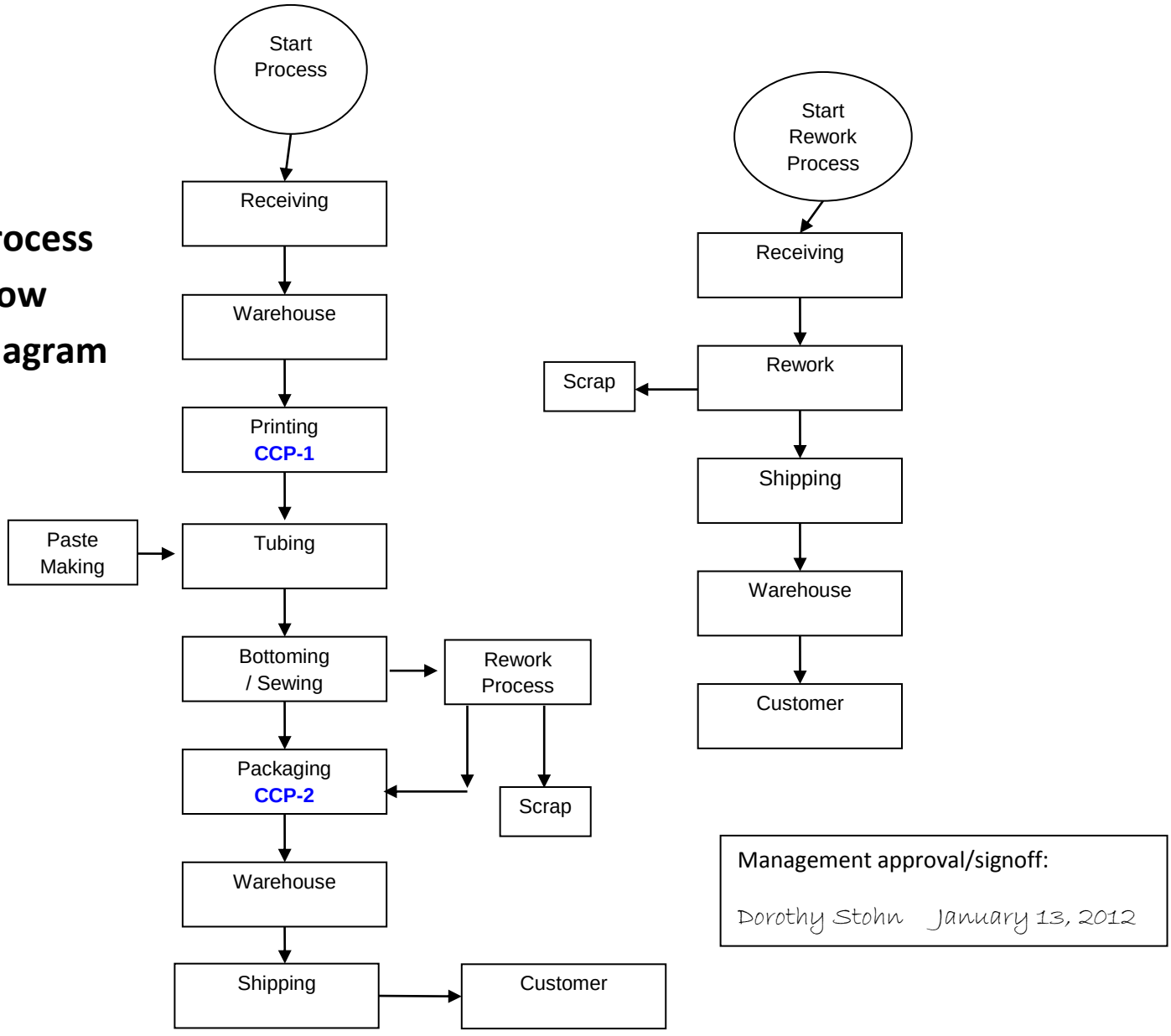
Product / Category Description	
Facility Name: Koyukuk Brands, Wiseman, AK	**Date** : November 23, 20xx
Product/ Product Category:	Multiwall Packaging
Product description:	Printed Multiwall packaging (e.g., Pinch Bottom Open Mouth (PBOM), Satchel Bottom Open Mouth, Sewn Open Mouth, or Pasted Valve). Packaging constructed typically of multiple plies of paper, sometimes with a film liner, and used to package food, ingredients, or pet food.
Process Flow:	Receipt of order, Graphics development and verification, Receipt of raw materials, Printing, Tubing, Bottoming, Packaging, Shipping
Food Safety Characteristics:	Based on risk assessment and end use (e.g., microwave popcorn hot oil leakage, needle breakage for sewn bags). Direct/Indirect/Non-food contact. Applied labeling (if any) must be accurate to prevent/eliminate mislabeling of finished products that could lead to allergen and/or regulatory food safety labeling non-compliance. Measures must also be instituted for the prevention of introduction of foreign objects such as metal contamination or accumulated debris.
Customer/ Consumer Use:	Finished bags to be used for containing food, ingredients, or pet food. Consumer/customer to open bag and remove product 1) in its entirety or 2) as needed for use.
Target Market:	Food or Pet industry
General Raw Materials:	Paper, film, inks, photopolymer plates, adhesives, string
Packaging/Palletization:	Pallets, corrugated boxes, stretch wrap, cardboard/corrugated slip sheets, cardboard corner boards, poly shrouds, banding
Shelf Life:	Typically not specified but recommended to be no greater than one year dependent on storage conditions.
Storage & Distribution:	Material stored at plant warehouse, distributed to food manufacturing plants/pet food manufacturing plants at ambient temperature. -20^{0}F - 120^{0}F, protect from moisture
Other:	No additional information

Preparing a HACCP Plan (continued)

Step 3: Create Process Flow Diagram (PFD)

a. Block Diagram showing manufacturing steps
b. Include Receipt of Raw Materials and Shipping of Finished Goods
c. Document: Process Flow Diagram
d. Note: Add CCPs to PFD after Step 6 (if any)

Process Flow Diagram

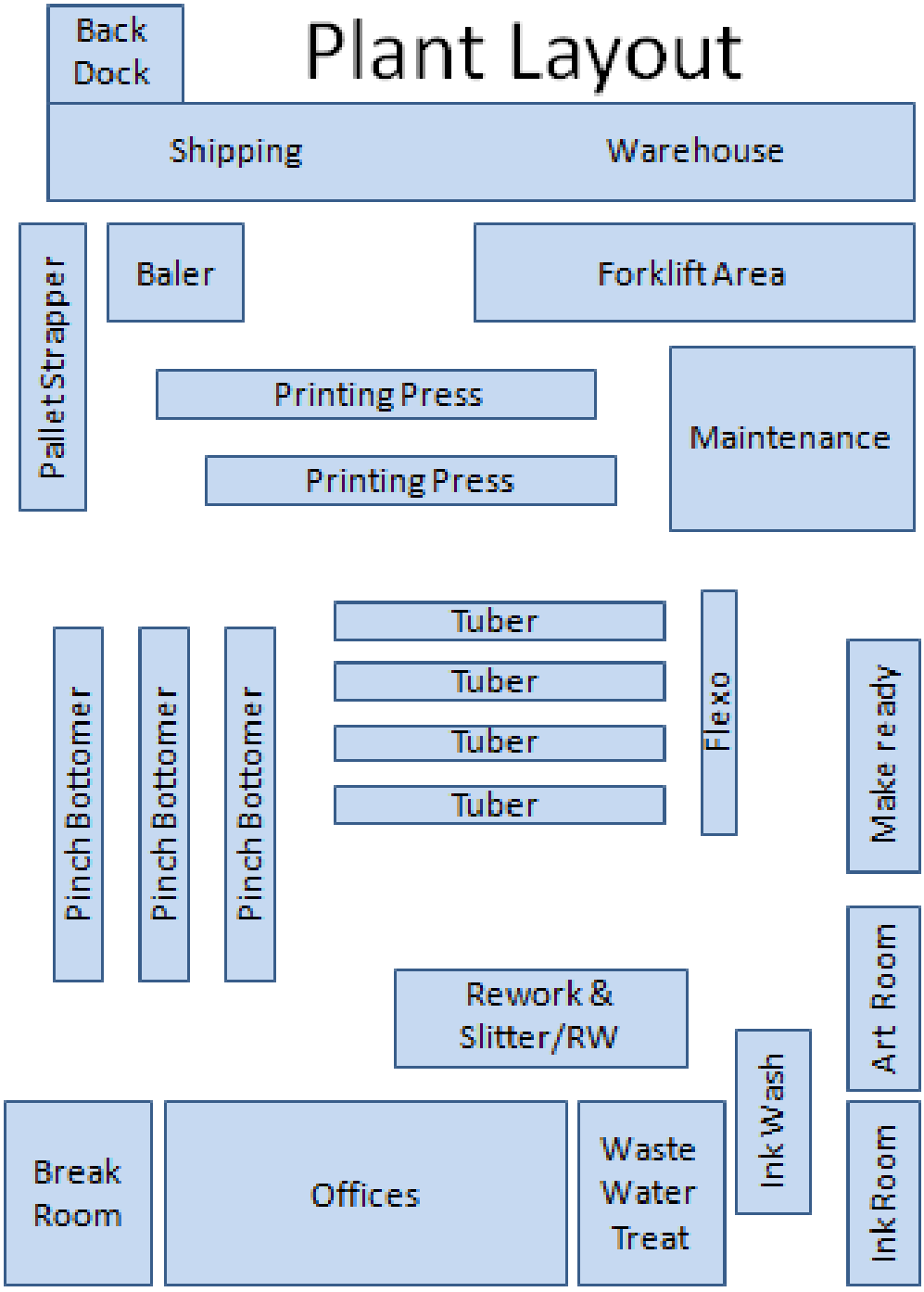


Management approval/signoff:

Dorothy Stohn January 13, 2012

North

Optional: include facility layout diagram for reference
(may also include traffic flows for materials and people)



Preparing a HACCP Plan (continued)

Step 4: Verify Accuracy of Process Flow Diagram

a. Team walks through plant with PFD
b. Confirm PFD with team and facility personnel
c. Make necessary changes before proceeding
d. Document: Edited Process Flow Diagram / Signed & Dated showing approval

Step 5: Perform Hazard Analysis

a. Evaluate *raw materials* for Chemical, Physical, Biological Hazards
b. Evaluate *processes* for Chemical, Physical, Biological Hazards
c. Document: Hazard Analysis Sheet for Raw Materials
d. Document: Hazard Analysis Sheet for Processes

List every Bill of Material used in the manufacturing process for population into Column 1 of Raw Material Hazard Analysis table.

Instructions: Identify potential hazards associated with incoming materials and rework. Assess to the best of your knowledge the likely risk associated with these materials and identify any specific preventive programs or corrective steps that eliminate or reduce those risks to an acceptable level.

Step 6: Determine Critical Control Points (CCPs)

a. Use CCP Decision Tree (see Appendix B)
b. Confirm CCPs Using CCP Definition
c. Document: Raw Materials / Process Hazard Analysis Worksheets
d. Document: CCPs on HACCP Master Plan

Raw Material Hazard Analysis

Facility Name: Koyukuk Brands -- Wiseman, AK				**Date:** Dec. 8, 20xx		
1	2		3	4	5	6
List each raw material/ ingredient in the process	**Does this material / ingredient INTRODUCE a potential food safety hazard? What is it?** C =Chemical P = Physical B = Biological		**Is this hazard CONTROLLED by a Pre-requisite Program or process step?** If YES, indentify the program or process. If a pre-requisite program or process is identified, do not complete Columns 4-6 and go to next process step. If NO, go to column 4.	**Is this hazard ELIMINATED by a subsequent process step?** If YES, this step is NOT a CCP. Indentify the subsequent process step in Column 5 and proceed to the next process step. If the hazard is eliminated at this step, enter NO and go to column 6 and assign a CCP #.	**Identify the last process step that will eliminate the potential hazard.** (Example: metal detector, filter, etc…)	**Assign a CCP # when the answer in Column #4 is NO.** (otherwise leave blank)
Films (BOPP, HDPE, LDPE & LLDPE)	C	No				
	P	Yes – Foreign Material	Yes – Receiving Inspections			
	B	No				
Adhesives (starch, hotmelt, lamination)	C	No				
	P	Yes – Foreign Material	Yes – Receiving Inspections			
	B	Yes – Infestation	Yes – Receiving Inspections			
String	C	No				
	P	No				
	B	No				
Ink and coatings	C	Yes – Plant Chemical	Yes – Chemical Control Plan			
	P	No				
	B	No				
Graphics and plates	C	No				
	P	No				
	B	No				
Paper (various types and grades)	C	No				
	P	Yes – Foreign Material	Yes – Receiving Inspections			
	B	Yes – Mold	Yes – Receiving Inspections and Quarterly Testing			
Packing Materials	C	No				

	P	No				
	B	Yes – Infestation and Mold	Yes – Receiving Inspections			
Rework (no different materials – same materials as above)	C	No				
	P	No				
	B	No				

Process Hazard Analysis

Facility Name: Koyukuk Brands -- Wiseman, AK			**Date:** Dec. 8, 20xx		
1	2	3	4	5	6
List each process step from the Process Flow Diagram (Also, bring forward each **Critical Ingredient** from the RM Hazard analy.)	**Does this ingredient or process step INTRODUCE a potential food safety hazard? What is it?** (Be as specific as possible) C =Chemical P = Physical B = Biological	**Is this hazard CONTROLLED by a Pre-requisite Program or process step?** If YES, indentify the program or process. If a pre-requisite program or process is identified, do not complete Columns 4-6 and go to next process step. If NO, go to column 4.	**Is this hazard ELIMINATED by a subsequent process step?** If YES, this step is NOT a CCP. Indentify the subsequent process step in Column 5 and proceed to the next process step. If the hazard is eliminated at this step, enter NO and go to column 6 and assign a CCP #.	**Identify the last process step that will eliminate the potential hazard.** (Example: metal detector, filter, etc…)	**Assign a CCP # when the answer in Column #4 is NO.** (otherwise leave blank)
Receiving	C No				
	P Yes – Foreign Material	Yes – Receiving Inspections			
	B No				
Warehousing	C No				
	P Yes – Foreign Material	Yes – Receiving Inspections			
	B No				
Printing	C Yes – Incorrect Design (allergen)	Yes – Design control checklists			
	Yes – splice error (wrong allergen info)	Yes – Splicing procedure			
	Yes – line clearance (mix design/allergen)	No	No	Line Clearance	CCP-1

	P	No				
	B	No				
Paste Making	C	Yes	Check valves in place for main water supply and hoses			
	P	No				
	B	Yes	Check valves in place for main water supply and hoses			
Tubing	C	Yes – Mixed Orders (allergen)	Yes – line clearance procedure			
	P	Yes – Contamination (choke hazard from chunk of accumulated perforator debris)	Yes – housekeeping standards			
	B	No				
Bottoming and/or Sewing	C	No				
	P	Yes – broken needles (choke or puncture hazard)	Yes – housekeeping standards + startup/quality checklists			
	B	No				
Packaging	C	Yes – Incorrect unitizing or palletizing (allergen)	No	No	Visual Inspection and Pallet Control	CCP-2
	P	No				
	B	No				
Warehousing	C	No				
	P	No				
	B	Yes – contamination/infestation	Housekeeping and IPM programs			
Shipping	C	No				
	P	No				
	B	Yes – contamination/infestation	Housekeeping and IPM programs			
Rework (no new steps – repeat of above steps)	C	No				
	P	No				
	B	No				

Preparing a HACCP Plan (continued)

Step 7: Establish Critical Limits for CCPs (if applicable)

a. Critical Limits must be meaningful; should be measurable
b. Document: HACCP Master Plan

Step 8: Establish Monitoring Procedures for CCPs (if any)

a. Identify how Critical Limits will be monitored; by whom; frequency; documentation requirements
b. Training for those performing the CCP monitoring
c. Documents: HACCP Master Plan

Step 9: Establish Corrective Actions for CCP Deviations (if applicable)

a. Identify Corrective Action for CCP checks falling outside of Critical Limits
b. Evaluation of products from previous CCP check
c. Document: HACCP Master Plan

Step 10: HACCP Plan Validation

a. Are CCPs meaningful, measurable?
b. Have all risks been identified, evaluated?
c. Have raw materials changed?
d. Has process or equipment changed?
e. Documents: Reassessment Log / Change Log / History / Meeting Minutes

HACCP Master Plan

Facility Name: Koyukuk Brands -- Wiseman, AK	**Date:** **Dec. 8, 20xx**

HACCP plan for Multiwall Bags

CCP Number	Significant Hazard	Critical Limit	Monitoring				Corrective Action	Verification	Record(s)
			What	**How**	**Frequency**	**Who**			
CCP-1 Line clearance	Printed materials from previous jobs have not been fully cleared (could lead to allergen declaration mistake)	No materials from other jobs allowed in area	Line clearance procedure	Operator removes all materials from previous order before new job starts up Detailed checklist is used to verify that all prior run materials are cleared from the line	Each work order	Operator	Operator removes materials per critical limits and re-inspects line. Signs off production record.	Verified by operator or other co-worker	Production records
CCP-2 Pallet and work order control	Incorrect unitizing or palletizing due to inadvertent mixing of bags results in allergen risk due to mixed product types	No mixing of bags	Visual inspection coupled with pallet clearance and segregation	Work instruction for operators/helpers Checklist completed	Every pallet	Operator	Segregate affected pallets. Withdraw or recall material if needed.	Verified by operator or other co-worker. Verify checklist completed.	Production records

Approval Signatures/ Dates

Facility Manager: D. Stohn December 14, 20xx

Quality Assurance Manager: M. Starcke December 14, 20xx

HACCP Plan Verification and Validation

In short, Verification confirms that the HACCP plan is being followed and Validation confirms that the HACCP plan properly addresses the appropriate activities. Verification and Validation activities must be documented.

Verification: Includes activities such as: an annual internal (or external) audit to confirm the HACCP plan is being followed as written; confirmation of operator training; confirmation of operator competence with respect to monitoring CCPs and addressing out-of compliance occurrences; HACCP record review; previous HACCP plan audits; and, spot-checking prerequisite program. Verification assures that the HACCP plan is operating effectively on a day-to-day basis.

OPTIONAL—INSERT HACCP VERIFICATION SCHEDULE

***Example*: HACCP Plan Verification Schedule**

Activity	Frequency	Responsibility	Reviewer
Initial Review of HACCP Plan	Prior to and during initial implementation of plan	3rd Party Auditor	HACCP Team
Verification Activities Scheduling	Yearly or upon HACCP System change	HACCP Coordinator	Plant Manager
Subsequent Review of HACCP Plan	When Critical Limits changed, significant changes to process, equipment changed, after system failure, etc.	3rd Party Auditor	HACCP Team
Verification of CCP Monitoring as Described in the Plan	According to HACCP Plan	According to HACCP Plan	According to HACCP Plan
Review of Monitoring Corrective Action Records to Show Compliance with the Plan	Quarterly	Quality Assurance	HACCP Team
Comprehensive HACCP System Verification	Yearly	3rd Party Auditor	Plant Manager

Validation: Includes activities such as: critical review of the hazard analysis for depth and accuracy (i.e., were all hazards considered? Were the correct CCPs chosen?); critical evaluation of the CCPs (i.e., are critical limits meaningful and actionable?); and, monitoring activities (i.e., are the correct parameters monitored at the correct frequency?). Validation provides evidence that the techniques and methods adopted by the plant are not just effective in theory, but will in fact work for the specific plant.

HACCP Plan Verification and Validation (continued)

OPTIONAL—INSERT HACCP VALIDATION SCHEDULE

***Example*: HACCP Plan Validation Schedule**			
Activity	Frequency	Responsibility	Reviewer
Were all hazards considered?	Yearly or when Critical Limits changed, significant changes to process, equipment changed, after system failure, etc.	HACCP Team	Plant Manager
Were correct CCP's chosen?	Yearly or when Critical Limits changed, significant changes to process, equipment changed, after system failure, etc.	HACCP Team	Plant Manager
Are Critical Limits meaningful/ actionable?	Yearly or when Critical Limits changed, significant changes to process, equipment changed, after system failure, etc.	HACCP Team	Plant Manager
Are the correct parameters monitored at the correct frequency?	Yearly or when Critical Limits changed, significant changes to process, equipment changed, after system failure, etc.	HACCP Team	Plant Manager

HACCP Plan Reassessment

The HACCP plan needs to be reassessed on an annual basis at minimum and/or when there are: changes to the plant; changes in key processing equipment; changes to primary raw materials; industry alerts concerning materials, processes, or equipment; industry/facility recalls; repeated/trended customer complaints; and; any change in materials, processing, or equipment that would lead to challenges to the HACCP Plan Validation.

Appendix C - HACCP Plan Validation/Reassessment Checklist

Various HACCP Forms

Blank copies of documents are available on the FSAP website:
www.foodsafetyallianceforpackaging.com

Appendices

Appendix A – Prerequisite Programs (*see FSAP website for more complete descriptions***)**

1) Good Manufacturing Practices (GMP): The goal of a Good Manufacturing Practices Program is to successfully organize, maintain and operate a sanitary process and environment in the facility.

2) Cleaning/Sanitation Program: The goal of the Cleaning/Sanitation Program is to maintain a sanitary environment, necessary for the production of food packaging of the highest quality and safety.

3) Chemical Control: The goal of the Chemical Control Program is to eliminate the possibility of contamination of food contact surfaces and finished products with non food grade substances. The Chemical Control Program also protects employees and the production area from exposure to hazardous chemicals.

4) Glass / Brittle Plastics / Ceramics Control: A program to replace or track the uses of glass, brittle plastics and ceramics in production should be in place. The program should be audited at least monthly. A list of irreplaceable glass or brittle plastic objects should be used as part of the audit.

5) Pest Control: The goal of the Pest Control Program is exclude pests from the plant, specifically, rodents, insects and birds. The Pest Control Program is carried out through a licensed pest control company, which meets all Federal, State, and Local regulatory requirements or by a licensed employee.

6) Record Keeping / Document Control: The facility should maintain a record-keeping program that will have information on file based on policy. This program ensures records are adequate to confirm conformance to specified standards and to demonstrate the quality system is effective.

7) Preventative Maintenance: This program is designed to inspect and prepare equipment to ensure precision performance.

8) Safety / MSDS: The facility should maintain an MSDS program and not allow chemicals to enter the facility without being accompanied by a Material Data Safety Sheet.

9) Allergen Awareness / Management: The level of implementation of this PP will be dependent upon whether or not allergens such as wheat starch are present in the processing environment. Many packaging plants will not have allergens in the processing areas, but will have allergens present in other areas such as lunch rooms and office areas. For printed items, ingredient statement will list allergenic ingredients and must be correct 100% of the time. There is no margin of error for incorrect copy or mixed items.

10) Process Control: All employees are part of facilitating a Quality Assurance program to ensure 100% compliance to the company and customer standards.

11) Line Clearance: All labels, packing materials, documentation, and previous products (i.e. clear conveyors, remove partial pallets and boxes, remove samples) run shall be removed from the machine and surrounding area prior to bringing materials for the next job to the work area.

Appendix A – Prerequisite Programs (*continued*)

12) Product Recall / Mock Recall Program: The goal of the Product Recall Program is to protect the customer from the possible event of a product safety failure by removing all suspect products from the distribution channels in the least amount of time, once a product recall or withdrawal is warranted and initiated. A mock recall should be performed (forwards to customer and backwards to supply item) at least annually.

13) Internal Audits: The facility shall follow a strict documented self-auditing program, which involves the participation of all managers to be audit ready and in compliance. The program should include:

14) Customer Complaints: The goal of the Customer Complaint Program is to resolve all customer complaints quickly, completely, and to the satisfaction of the customer and the plant.

15) Certificates of Analysis (COA): The facility will maintain a Certificate of Analysis program. The facility will not allow any chemicals, raw materials, or label material to be used in the process without being accompanied by a COA or COC (Certificate of Compliance).

16) Letters of Guarantee (LOG): The facility will maintain a Letter of Guarantee program. The facility will not allow any chemicals, raw materials, or label material to be used in the process without being accompanied by a LOG.

17) Microbiological Control: Materials and or processes presenting a risk of undesirable micro growth should be monitored and controlled. For example, if the facility uses water-based processing aids (i.e., mandrel lubricants), the potential for *Pseudomonas* to be present in excess amounts in water based products is checked by sending samples to an outside laboratory for analysis. Samples should be taken from the lubricant storage, line pots, and final product. The analysis should include: sample name; condition upon receipt, value with units, control result, acceptance limits (if established).

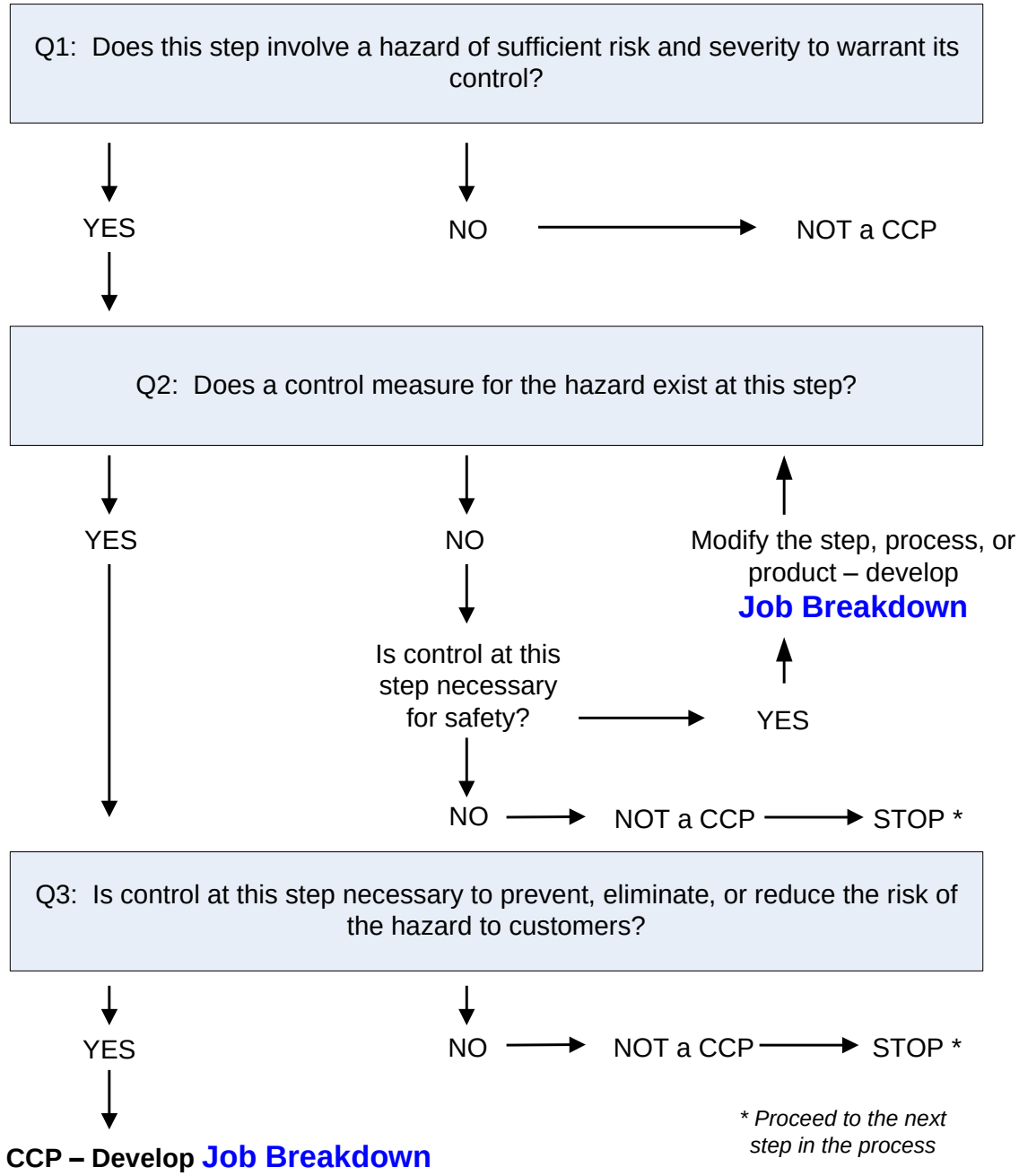
18) Packaging Security: The supplier shall have security systems in place to ensure the security of the workplace and products. Packaging Security audits shall occur at least yearly and when there are major changes to the building or equipment.

Appendix B – CCP Decision Tree

Example of a CCP Decision Tree

Important considerations when using the Decision Tree:

1. The Decision Tree is used after the Hazard Analysis
2. The Decision Tree is used at the steps where a Significant Hazard has been identified
3. A subsequent step in the process may be more effective for controlling a hazard and may be the preferred CCP
4. More than one step in a process may be involved in controlling a hazard
5. More than one hazard may be controlled by a specific control measure



Appendix C – HACCP Validation / Reassessment Checklist

HACCP Validation/Reassessment Checklist (adapted from an NCIMS form)

SUBJECT	ISSUE DATE	PRODUCT
HACCP Validation/Reassessment Checklist		
PLANT NAME	SUPERSEDES	PAGE

Validation Type (check one):

○	Initial Validation (within 12 months of implementation)
○	Validation (Reassessment) due to changes made in raw materials or source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or intended consumers of the finished product and rate or type of consumer complaints.
○	Annual Validation (Reassessment) of the HACCP plan including Hazard Analysis

Date Conducted:

Conducted By:

Topic	Yes	No	If "Yes," Describe	Food Safety Implication?	Are modifications to the HACCP system required?
1. Evaluate product & process					
Product description changed, e.g., intended use, consumer?	○	○			
Formula changed?	○	○			
Ingredients / Packaging changed?	○	○			
Any new product consumption or storage methods?	○	○			
Any new suppliers?	○	○			
Process flow changed?	○	○			
Equipment / computer software changed?	○	○			
Finished Product Distribution changed?	○	○			
Other, e.g., production volume increased:	○	○			
2. Evaluate product / process history					
Repeat CCP deviations?	○	○			
Any recent industry recalls of similar product since the last annual	○	○			
New or emerging hazards, e.g., recent CDC Morbidity & Mortality	○	○			
Regulatory Agency recommendations, e.g., guidance	○	○			
Any confirmed food safety consumer complaints?	○	○			
Other:	○	○			

Topic	Yes	No	If "No," Describe	Food Safety Implication?	Are modifications to the HACCP system required?
3. Evaluate adequacy of CCPs, critical limits, monitoring, corrective action, CCP verification, and record keeping procedures. Review current CCP documentation.					
Do the CCPs control the hazards?	○	○			
Are the CCP critical limits adequate?	○	○			
Do monitoring methods and frequency demonstrate control?	○	○			
Do corrective actions properly address affected product and correct	○	○			
Does validation include review of consumer complaints?	○	○			
Other, e.g., Prerequisite Programs or procedures may affect the hazard	○	○			

Appendix D – HACCP Plan Reassessment Change Form

HACCP PLAN REASSESSMENT CHANGE FORM

Facility Name:		**Person(s) Responsible:**	
HACCP Plan Name/Number and Date:			

During the reassessment of this plan, the person(s) responsible listed above has/have determined that Changes, Additions, or Deletions were needed. Those changes are documented below. Also attached is information used to support modification(s) of this plan.

Check One:		**CHANGE**		**ADDITION**		**DELETION**

What specifically were Changed / Added / Deleted?
Why was it Changed / Added / Deleted?
What is the basis for the Change / Addition / Deletion?

Appendix E – Examples of Verification Activities

Examples of Verification Activities

A. Verification procedures may include:
    1. Establishment of appropriate verification schedules.
    2. Review of the HACCP plan for completeness.
    3. Confirmation of the accuracy of the flow diagram.
    4. Review of the HACCP system to determine if the facility is operating according to the HACCP plan.
    5. Review of CCP monitoring records.
    6. Review of records for deviations and corrective actions.
    7. Review of critical limits to confirm that they are adequate to control significant hazards.
    8. Review of HACCP plan, including on-site review.
    9. Review of modifications of the HACCP plan.
    10. Sampling and testing to verify CCPs.
B. Verification should be conducted:
    1. Routinely, or on an unannounced basis, to assure CCPs are under control.
    2. When there are emerging concerns about the safety of the product.
    3. When foods have been implicated as a vehicle of food borne disease.
    4. To confirm that changes have been implemented correctly after a HACCP plan has been modified.
    5. To assess whether a HACCP plan should be modified due to a change in the process, equipment, ingredients, etc.
C. Verification reports may include information on the presence and adequacy of.
    1. The HACCP plan and the person(s) responsible for administering and updating the HACCP plan.
    2. The records associated with CCP monitoring.
    3. Direct recording of monitoring data of the CCP while in operation.
    4. Certification that monitoring equipment is properly calibrated and in working order.
    5. Corrective actions for deviations.
    6. Sampling and testing methods used to verify that CCPs are under control.
    7. Modifications to the HACCP plan.
    8. Training and knowledge of individuals responsible for monitoring CCPs.
    9. Review activities.

Appendix F - Examples of HACCP Records

Examples of HACCP Records

A. Raw materials / process steps for which critical limits have been established.
    1. Supplier certification records documenting compliance with a critical limit.
    2. Processor audit records verifying supplier compliance.
    3. Storage records (e.g., time, temperature) for when storage is a CCP.
B. Processing, storage and distribution records
    1. Information that establishes the efficacy of a CCP to maintain product safety.
    2. Data establishing the safe shelf life of the product; if age of product can affect safety.
    3. Records indicating compliance with critical limits when packaging materials, labeling or sealing specifications are necessary for food safety.
    4. Monitoring records.
    5. Verification records.
C. Deviation and corrective action records.
D. Employee training records that are pertinent to CCPs and the HACCP plan.
E. Documentation of the adequacy of the HACCP plan from a knowledgeable HACCP expert.

References

National Advisory Committee on Microbiological Criteria for Foods (NACMCF), 1998. Hazard Analysis and Critical Control Point Principles and Application Guidelines. *Journal of Food Protection*. 61: 1246-1259.

National Advisory Committee on Microbiological Criteria for Foods (NACMCF), 1997. Hazard Analysis and Critical Control Point Principles and Application Guidelines. Downloaded from FDA link on Internet.

National Food Processors Association, 1999. *HACCP – A Systematic Approach to Food Safety*. The Food Processors Institute, Washington, D.C.

U.S. Department of Agriculture, 1999. *Guidebook for the Preparation of HACCP Plans*. Food Safety and Inspection Service, Washington, D.C.

Packaging Association of Canada, Generic HACCP Plan Revision 3, 2007

The Food Safety Alliance for Packaging website, HACCP models and resource links www.iopp.org/fsap

PACsecure materials http://www.pac.ca/index.php/pac/pacsecure

http://www.brcglobalstandards.com/GlobalStandards/Home.aspx

U.S. FDA enforcement actions, recalls, and alerts http://www.fda.gov

The International Food Safety and Quality Network http://www.ifsqn.com/forum/

ASQ Food, Drug, and Cosmetic Division website http://asq.org/index.aspx

The Certified HACCP Auditor Handbook (John G. Surak & Steven Wilson, Editors)

Disclaimer

Implementation and or execution of this model will guide the user in the installation of a Food Safety system. It will not guarantee business from any of the former, current, and/or future FSAP member companies. Furthermore, the implementation and or execution of this model will not guarantee the safety of your product.