

HACCP: Hazard Analysis and Critical Control Points *A Food Safety Approach for Suppliers to the Food Industry*

Packaging HACCP Plan Model: **Folding Cartons**
FLDCRT1 Revision 05-06-2010



Prepared by representatives of the following companies:

Alcan Packaging

General Mills

Berry Plastics

Graham Packaging Company

Campbell Soup Company

Graphic Packaging

ConAgra Foods

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.

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, the National Aeronautics and Space Administration.

2. Why is HACCP Needed for Packaging Suppliers?

Suppliers of packaging to food producing companies are part of the food industry. Food Safety starts at the packaging supplier 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 of 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 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 sections 11 through 20 of this document, the plant will have implemented a basic HACCP program. The plant 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 plant’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 requires 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.
 - i. CCP Validation/Verification plan: See section 21.
- e. **CP:** Control Point - Any step at which biological, chemical, or physical factors can be controlled.
- f. **QCP:** Quality Control Point - A step in the process where a quality parameter may be controlled.
- g. **PP:** 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. Examples and more information are provided in Appendix A.

7. Common Approach for HACCP Implementation

Action steps appear as Items 11 – 20 in this model
--

- a. Assemble HACCP Team (multi-disciplinary)
See Item 11, Step 1
- b. Write Product Description (how is it made and what raw materials are used)
See Item 12, Step 2
- c. Identify Target Audience (include markets and customers)
See Item 12, Step 2
- d. Create Process Flow Diagram
See Item 13, Step 3
- e. Verify Process Flow Diagram
See Item 14, Step 4
- f. Identify Hazards
See Item 15, Step 5
- g. Perform Hazard Analysis
See Item 15, Step 5
- h. Determine if Critical Control Points (CCP) exist. *(Some processes will not have CCPs)*
See Item 16, Step 6
 - 1. Use CCP Decision Tree *(See Appendix B)*
- i. Establish Critical Control Point Limits (if applicable)
See Item 17, Step 7
- j. Establish Monitoring Procedures for Critical Control Points (if applicable)
See Item 18, Step 8
- k. Establish Corrective Actions for Critical Control Point Deviations (if applicable)
See Item 19, Step 9
- l. Verify HACCP Plan
See Item 20, Step 10

8. Applying the Packaging HACCP Model

- a. This model should be used for any Folding Carton Manufacturer who supplies goods and services to the Food Industry
- b. It must be noted the Critical Control Points outlined in this model are only POTENTIAL CCPs. Your plan may/will vary depending on your exact process, programs and customer requirements.

9. HACCP Training

- a. HACCP Team Leader – It is recommended that this person has formal training from an accredited organization. (See FSAP website)
- b. HACCP Team Members – Team members should receive formal documented training from the team leader or person knowledgeable in HACCP.
- c. Plant Employees – Should receive documented training upon hiring and at least annually thereafter.
- d. Those with CCP Monitoring Responsibility – Shall receive documented training specific to the CCP they monitor in addition to annually plant-wide training.
- e. Training Records – HACCP training must be documented and the records maintained per the plant 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: Expected documentation is listed in section 11 – 20 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 (Appendix A).
- b. Completing HACCP Records: HACCP records shall be completed at the time of use. Information shall 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 YOUR HACCP PLAN

11. Step 1: Assemble HACCP Team

- a. Cross Functional Team
- b. Management Sponsorship / Buy-In / Participation
- c. HACCP Training
- d. Documents: Team List / Charter with Management Sign-Off / Generic Facility Training Log

Facility HACCP Team

Facility Name: <i>StanLee Packaging, Marvel Facility</i>		Date: <i>June 30, 20XX</i>	
Team Member Name	Department	Title	HACCP Team Role
<i>C. Kent</i>	<i>Food Safety</i>	<i>Food Safety Manager</i>	<i>Coordinator</i>
<i>D. Prince</i>	<i>Quality</i>	<i>Quality Manager</i>	<i>Member</i>
<i>S. Kyle</i>	<i>Production</i>	<i>Winder Operator</i>	<i>Member</i>
<i>B. Banner</i>	<i>Maintenance</i>	<i>Maintenance Shift Supervisor</i>	<i>Member</i>
<i>P. Parker</i>	<i>Technical</i>	<i>Engineer</i>	<i>Member</i>
<i>C. Kent</i>	<i>Food Safety</i>	<i>Food Safety Manager</i>	<i>Coordinator</i>

Facility HACCP Charter

Facility Name: StanLee Packaging, Marvel Facility

Date: June 30, 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
HACCP Team Leader	C. Kent	<i>C. Kent</i>
Management Representative	L. Jefe	<i>L. Jefe</i>
HACCP Team Member	D. Prince	<i>D. Prince</i>
HACCP Team Member	S. Kyle	<i>S. Kyle</i>
HACCP Team Member	B. Banner	<i>B. Banner</i>
HACCP Team Member	P. Parker	<i>P. Parker</i>
HACCP Team Member	B. Wayne	<i>B. Wayne</i>

Facility Training Log

Subject	<i>HACCP Hazard Analysis</i>		
Date(s)	<i>July 15, 20XX</i>		
Trainer's Name & Title	<i>C. Kent - Food Safety Manager</i>		
Materials Used	<i>CCP Decision Tree, Internal SOPs</i>		
Print Name	Title	Date	Trainer
R. Secrest	Plant Manager	7/15/20XX	
P. Abdul	Quality Systems Engineer	7/15/20XX	
S. Tyler	Maintenance Supervisor	7/15/20XX	
J. Lopez	Customer Technical Service	7/15/20XX	
S. Cowell	CI Coordinator	7/15/20XX	
R. Jackson	Quality Manager	7/15/20XX	

12. Step 2: Write Product Description

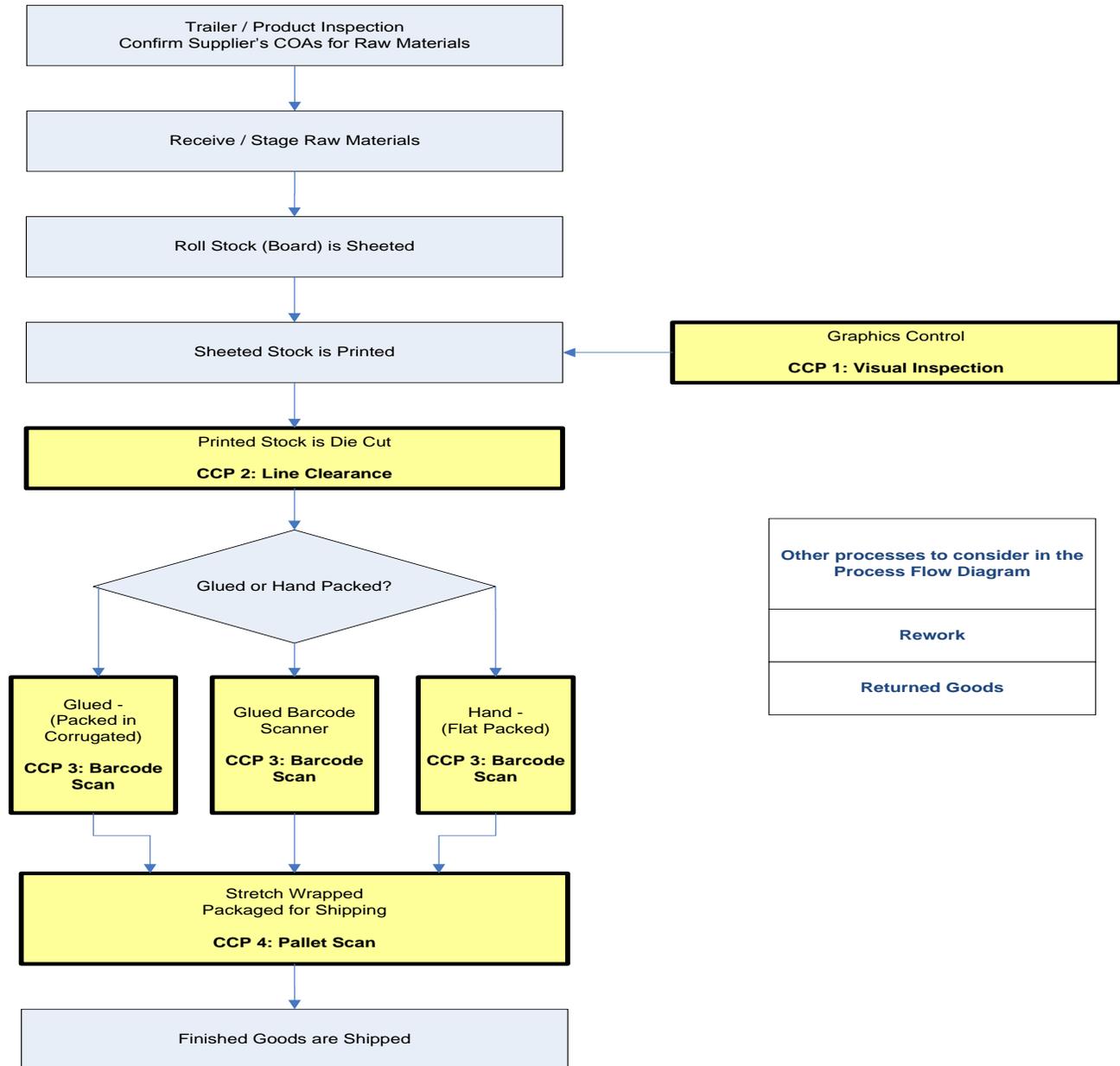
- What do you make
- How do you make it
- Intended usage (include time and temperature as applicable)
- What Raw Materials are used
- Intended markets / customers
- Document: Written Descriptions of what is made and production process

Product / Product Category Description

Facility Name: <i>StanLee Packaging, Marvel Facility</i>		Date: <i>July 30, 20XX</i>
Product/Product Category	<i>Printed paperboard folding cartons for food packaging (e.g., Name, type, size).</i>	
Process	<i>Paperboard Converting, Recycled roll stock printed, cut and scored, flat packed or side seam glued.</i>	
Food Safety Characteristics	<i>Direct/Indirect/Non- Food Contact. Applied labeling (if any) must be accurate to prevent/eliminate the potential for 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.</i>	
Customer Use	<i>Finished product containers for food, household items, and consumer packaging.</i>	
Target Market/Consumer	<i>Food Processors, Packaging for indirect food products.</i>	
General Raw Materials	<i>Kraft (bleached / non bleached), Paperboard • Sulfite paperboard (bleached / non bleached), Clay-coated, recycled board, ink and coatings, glue.</i>	
Packaging/Palletization	<i>Protective corrugated sheets, Printed paperboard packaging (recycled materials) bulk stacked with corrugated or paperboard dividers and shrink wrapped or pre-glued and case packed, stacked on corrugate dividers and stretch wrapped Pallets (e.g. wood, etc..), Labels (shipping, product, paper), (e.g., Preparation, storage needs, use by, best when used by)</i>	
Shelf Life	<i>Depends upon end product and customer requirements. Shelf life is very dependant on storage environment. Cartons are generally warranted for manufacturability for 90 days.</i>	
Storage & Distribution	<i>Warehousing, transportation - trucking, rail, containers, Cartons are stored in the producing facility and offsite warehouse and distributed to customer packaging plants. Materials should be stored in ambient conditions.</i>	
Other	<i>None (in this example)</i>	

13. Step 3: Create Process Flow Diagram (PFD)

- Block Diagram showing manufacturing steps
- Include Receipt of Raw Materials and Shipping of Finished Goods
- Document: Process Flow Diagram
- Note: Add CCPs to PFD after Step 6



14. Step 4: Verify Accuracy of Process Flow Diagram (PFD)

- Team walks through plant with PFD
- Confirm PFD with team and plant floor workers
- Make necessary changes before proceeding
- Document: Edited Process Flow Diagram / Signed / Approved

15. 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.

Raw Material Hazard Analysis

Facility Name: <i>StanLee Packaging, Marvel Facility</i>	Date: <i>August 24, 20XX</i>
---	-------------------------------------

1	2	3	4	5	6
List each raw material/ingredient in the process	Does this material/ingredient INTRODUCE a potential food safety hazard? Identify here. (Be as specific as possible when listing the hazard.) C = Chemical P = Physical B = Biological	Is this hazard CONTROLLED by a Prerequisite Program or process step? If YES, identify the Program or process. If a Prerequisite 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 (later) process step? If YES, this step is NOT a CCP. Identify the subsequent process step in Column 5 and proceed to the next process step. If the hazard is eliminated at this step (no subsequent elimination step) enter NO and go to Column 6 and assign a CCP number.	Identify the last process step that will eliminate the potential hazard. (Example: metal detector, filter, etc.).	Assign a CCP number when the answer in Column 4 is NO. Otherwise leave blank.
Paper Board	C: Oil, Grease, Solvents	<i>Yes - COC's, Letter of Guarantee</i>			
	P: Foreign Material	<i>As above</i>			
	B: ---				
Printing Inks	C: Heavy Metals	<i>Yes - COC's, Letter of Guarantee</i>			
	C: Off-flavor/odor	<i>Yes - Letters of guaranty from supplier.</i>			

1	2	3	4	5	6
List each raw material/ingredient in the process	Does this material/ingredient INTRODUCE a potential food safety hazard? Identify here. (Be as specific as possible when listing the hazard.) C = Chemical P = Physical B = Biological	Is this hazard CONTROLLED by a Prerequisite Program or process step? If YES, identify the Program or process. If a Prerequisite 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 (later) process step? If YES, this step is NOT a CCP. Identify the subsequent process step in Column 5 and proceed to the next process step. If the hazard is eliminated at this step (no subsequent elimination step) enter NO and go to Column 6 and assign a CCP number.	Identify the last process step that will eliminate the potential hazard. (Example: metal detector, filter, etc.).	Assign a CCP number when the answer in Column 4 is NO. Otherwise leave blank.
	C: Chemical migration	<i>Yes-Letters of guaranty from supplier.</i>			
	P: --				
	B: --				
Coatings	C: Heavy Metals	<i>Yes - COC's, Letter of Guarantee</i>			
	C: Off-flavor/odor	<i>Yes-Letter of guaranty from supplier</i>			
	C: Chemical Migration	<i>Yes-Letter of guaranty from supplier</i>			
	P: --				
	B: --				
Adhesives	C: Heavy Metals	<i>Yes - COC's, Letter of Guarantee</i>			
	P: --				
	B: --				
Shrink Wrap Film	C: --				
	P: --				
	B: --				
Tape	C: --				
	P: --				
	B: --				

1	2	3	4	5	6
List each raw material/ingredient in the process	Does this material/ingredient INTRODUCE a potential food safety hazard? Identify here. (Be as specific as possible when listing the hazard.) C = Chemical P = Physical B = Biological	Is this hazard CONTROLLED by a Prerequisite Program or process step? If YES, identify the Program or process. If a Prerequisite 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 (later) process step? If YES, this step is NOT a CCP. Identify the subsequent process step in Column 5 and proceed to the next process step. If the hazard is eliminated at this step (no subsequent elimination step) enter NO and go to Column 6 and assign a CCP number.	Identify the last process step that will eliminate the potential hazard. (Example: metal detector, filter, etc.).	Assign a CCP number when the answer in Column 4 is NO. Otherwise leave blank.
Pallets	C: --- Off-Odor	<i>Yes, Specification to exclude using wood preservatives, incoming inspection</i>			
	P: Foreign Material	<i>Yes - COC's, Incoming Pallet Inspection</i>			
	B: ---				
Plastic Banding	C: ---				
	P: ---				
	B: ---				
Corrugate Cases / Caps, Trays	C: ---				
	P: ---				
	B: ---				

Process Hazard Analysis

Facility Name: *StanLee Packaging, Marvel Facility*

Date: *August 24, 20XX*

1	2	3	4	5	6
<p>List each process step from the Process Flow Diagram.</p> <p><u>Also</u>, bring forward each ingredient from the Material Hazard Analysis Worksheet that was determined to be a Critical Ingredient.</p>	<p>Does this ingredient or process step INTRODUCE a potential food safety hazard? Identify here. (Be as specific as possible when listing the hazard.)</p> <p>C = Chemical P = Physical B = Biological</p>	<p>Is this hazard CONTROLLED by a Prerequisite Program or process step? If YES, identify the Program or process. If a Prerequisite Program or process is identified, do not complete Columns 4-6 and go to next process step. If NO, go to Column 4.</p>	<p>Is this hazard ELIMINATED by a subsequent (later) process step? If YES, this step is NOT a CCP. Identify the subsequent process step in Column 5 and proceed to the next process step. If the hazard is eliminated at this step (no subsequent elimination step) enter NO and go to Column 6 and assign a CCP number.</p>	<p>Identify the last process step that will eliminate the potential hazard. (Example: metal detector, filter, etc.).</p>	<p>Assign a CCP number when the answer in Column 4 is NO. Otherwise leave blank.</p>
Receiving	C: --				
	P: Foreign Material	<i>Yes - COC's, Letter of Guarantee</i>			
	B: --				
Sheeting	C: --				
	P: --				
	B: --				
Graphics Control	C: Error / Allergen: Wrong Copy	<i>No</i>	<i>No</i>	<i>Overlay check</i>	<i>CCP 1</i>
	P: --				
	B: --				
Printing	C: Error / Allergen: Mixed Cartons	<i>No</i>	<i>No</i>	<i>Line Clearance</i>	<i>CCP 2</i>
	C: Off-flavor/odor	<i>Yes-Process step: proper ink curing and solvent flashing-off, sniff test, and/or GC confirmation</i>			
	C: Chemical migration	<i>Yes-Process step: proper ink curing and solvent flashing-off, sniff test, and/or GC confirmation</i>			
	P: --				
	B: --				

1	2	3	4	5	6
<p>List each process step from the Process Flow Diagram.</p> <p>Also, bring forward each ingredient from the Material Hazard Analysis Worksheet that was determined to be a Critical Ingredient.</p>	<p>Does this ingredient or process step INTRODUCE a potential food safety hazard? Identify here. (Be as specific as possible when listing the hazard.)</p> <p>C = Chemical P = Physical B = Biological</p>	<p>Is this hazard CONTROLLED by a Prerequisite Program or process step? If YES, identify the Program or process. If a Prerequisite Program or process is identified, do not complete Columns 4-6 and go to next process step. If NO, go to Column 4.</p>	<p>Is this hazard ELIMINATED by a subsequent (later) process step? If YES, this step is NOT a CCP. Identify the subsequent process step in Column 5 and proceed to the next process step. If the hazard is eliminated at this step (no subsequent elimination step) enter NO and go to Column 6 and assign a CCP number.</p>	<p>Identify the last process step that will eliminate the potential hazard. (Example: metal detector, filter, etc.).</p>	<p>Assign a CCP number when the answer in Column 4 is NO. Otherwise leave blank.</p>
Cutting	C: Error / Allergen: Mixed Cartons				
	P: --	No	No	Line Clearance	CCP 2
	B: --				
Finishing / Gluing	C: Error / Allergen: Mixed Cartons	No	No	Line Clearance	CCP 2
	P: --				
	B: --				
Hand Packing	C: Error / Allergen: Mixed Cartons	No	No	Line Clearance	CCP 2
	P: --				
	B: --				
Glue / Folding	C: Error / Allergen: Mixed Cartons	No	No	Purge Process Bar Code Scanning	CCP 2 CCP 3
	P: --				
	B: --				
Hand Packing / Warehouse	C: Error / Allergen: Mixed Cartons	No	No	Purge Process	CCP 2
	P: --				
	B: --				
Shipping	C: Error / Allergen: Mixed Cartons	No	No	Pallet / Case Scan	CCP 4
	P: --				
	B: --				

16. Step 6: Determine Critical Control Points (CCPs)

- a. Use CCP Decision Tree (See Appendix A)
- b. Confirm CCPs Using CCP Definition on Page 3.
- c. Document: Product/Process Hazard Analysis Worksheets
- d. Document: CCPs on HACCP Master Plan

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

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

18. Step 8: Establish Monitoring Procedures for Critical Control Points (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

19. Step 9: Establish Corrective Actions for Critical Control Point 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

HACCP Master Plan

Facility Name: : <i>StanLee Packaging, Marvel Facility</i>	Date: <i>October 5, 20XX</i>
HACCP Plan Name / Number: <i>Folding Cartons / FLDCRT1</i>	

1	2	3	4	5	6	7	8	9	10
CCP	Significant Hazard	Critical Limit	Monitoring				Corrective Action(s)	Verification	Record(s)
			What	How	Frequency	Who			
1. Graphics Control	Mixed ingredients or mixed/wrong copy	Correct Item in Position on Printing Plate	Approved graphics	Overlay	Each	Graphics coordinator	Process stops until acceptable graphic records are received	Sign off on graphics 100% proof guarantee	Graphic sign offs
2a. Line Clearance	Mixed cartons	Zero mixed cartons	Purge process	Line Clearance at – change-over	Every Make Ready	Printing Dept	Line shut down/mixing investigation	Sort back to last good validation	Line Clearance sheets with Supv. sign offs
2b. Line Clearance	Mixed Cartons	Zero Mixed Cartons	Purge process	Line Clearance at – change-over	Every Make Ready	Cutting Dept	Line shut down/mixing investigation	Sort back to last good validation	Line Clearance sheets with Supv. sign offs
2c. Line Clearance	Mixed Cartons	Zero Mixed Cartons	Purge process	Line Clearance at – change-over	Every Make Ready	Finishing Dept	Line shut down/mixing investigation	Sort back to last good validation	Line Clearance sheets with Supv. sign offs
3. Bar Code Scanner	Mixed Cartons	Zero Mixed Cartons	Bar Code Scanner	Bar Code on carton flap	Every carton that is glued	Finishing Department	Line shut down/mixing investigation	Sort back to last good validation	Bar Code scanner verification sheets and Supv. sign offs
4. Pallet Scanning	Mixed cases on pallets	Zero Mixed cases on loads	Bar Code Scanner	Bar Code on Case Labels	Every Pallet that is shipped	Warehouse / Shipping	Loading of truck stops until pallet verified correct	Load is restacked and all cases verified correct	Load planning sheet with Supv. Sign off

Approved By: (Signature, Title, and Date)	<i>C. Kent, Food Safety Manager, October 12, 20XX</i>
--	---

20.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

21.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.

- a. 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 programs. Verification assures that the HACCP plan is operating effectively on a day-to-day basis.
- b. 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.

22.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 any materials, processing, or equipment that would lead to challenges to the HACCP Plan Validation.

23.Various HACCP Forms

Blank copies of documents presented in Sections 11 – 20 are available on the FSAP website: www.foodsafetyallianceforpackaging.com

HACCP Plan Reassessment Checklist

HACCP PLAN REASSESSMENT CHECKLIST

EXAMPLE (see *Process Flow Diagram* section below)

The purpose of this checklist is to provide a guide for reassessing a HACCP Plan. A complete and signed checklist provides documentation that a reassessment of a HACCP Plan has taken place. A HACCP Plan Reassessment Checklist should be completed for each HACCP Plan.

If changes are needed in any section of the HACCP Plan, a HACCP Plan Reassessment Form must be completed.

Facility Name:	: StanLee Packaging, Marvel Facility	Person(s) Responsible:	W. Wiksell, D. Reyes
HACCP Plan Name/Number and Date:	Folding Cartons / FLDCRT1		

PRODUCT DESCRIPTION(s):		
Reassessor(s): W. Wiksell, D. Reyes	Date: October 26, 20XX	
Changes Needed? (Choose Yes or No)	Yes	No
HACCP Plan Reassessment Change Form Completed?	Yes	No
Comments: New ink supplier for all process and line colors. Requires new process approval and change management process to be followed.		

TARGET AUDIENCE:		
Reassessor(s): W. Wiksell, D. Reyes	Date: October 26, 20XX	
Changes Needed? (Choose Yes or No)	Yes	No
HACCP Plan Reassessment Change Form Completed?	Yes	No
Comments: None		

PROCESS FLOW DIAGRAM:		
Reassessor(s): W. Wiksell, D. Reyes	Date: October 26, 20XX	
Changes Needed? (Choose Yes or No)	Yes	No
HACCP Plan Reassessment Change Form Completed?	Yes	No
Comments: None		

HAZARD ANALYSIS: (Each step in the process flow diagram must be addressed)		
Reassessor(s): <i>W. Wiksell, D. Reyes</i>	Date: <i>October 26, 20XX</i>	
Changes Needed? (Choose Yes or No)	Yes	No
HACCP Plan Reassessment Change Form Completed?	Yes	No
Comments: None		

IDENTIFICATION OF CRITICAL CONTROL POINTS:		
Reassessor(s): <i>W. Wiksell, D. Reyes</i>	Date: <i>October 26, 20XX</i>	
Changes Needed? (Choose Yes or No)	Yes	No
HACCP Plan Reassessment Change Form Completed?	Yes	No
Documentation on file to support selection of CCPs?	Yes	<i>No</i>
Comments: None		

ESTABLISHMENT OF CRITICAL LIMITS:		
Reassessor(s): <i>W. Wiksell, D. Reyes</i>	Date: <i>October 26, 20XX</i>	
Changes Needed? (Choose Yes or No)	Yes	No
HACCP Plan Reassessment Change Form Completed?	Yes	No
Documentation on file to support establishment of critical limits?	Yes	<i>No</i>
Comments: None		

MONITORING PROCEDURES:		
Reassessor(s): <i>W. Wiksell, D. Reyes</i>	Date: <i>October 26, 20XX</i>	
Changes Needed? (Choose Yes or No)	Yes	No
HACCP Plan Reassessment Change Form Completed?	Yes	No
Monitoring records are being filled out correctly?	Yes	<i>No</i>
Comments: None		

CORRECTIVE ACTION:		
Reassessor(s): <i>W. Wiksell, D. Reyes</i>	Date: <i>October 26, 20XX</i>	
Changes Needed? (Choose Yes or No)	Yes	No

HACCP Plan Reassessment Change Form Completed?	Yes	No
Corrective Action records are being filled out correctly?	Yes	No
Comments: None		

RECORD KEEPING PROCEDURES:		
Reassessor(s): <i>W. Wiksell, D. Reyes</i>	Date: <i>October 26, 20XX</i>	
Changes Needed? (Choose Yes or No)	Yes	No
HACCP Plan Reassessment Change Form Completed?	Yes	No
Accurate and current record keeping forms are being used?	Yes	No
Comments: None		

VERIFICATION PROCEDURES:		
Reassessor(s): <i>W. Wiksell, D. Reyes</i>	Date: <i>October 26, 20XX</i>	
Changes Needed? (Choose Yes or No)	Yes	No
HACCP Plan Reassessment Change Form Completed?	Yes	No
Documentation on file to support verification?	Yes	No
Comments: None		

Additional Comments or Observations:
New supplier certification and compliance documents needed. Certification process and change management process must be followed and HACCP validation completed. D. Reyes 10/26/20XX

HACCP Plan Reassessment Change Form

HACCP PLAN REASSESSMENT CHANGE FORM

EXAMPLE

Facility Name:	<i>: StanLee Packaging, Marvel Facility</i>	Person(s) Responsible:	<i>W. Wiksell, D. Reyes</i>
HACCP Plan Name/Number and Date:	<i>Folding Cartons / FLDCRT1</i>		

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:	<input type="checkbox"/>	CHANGE	<input checked="" type="checkbox"/>	ADDITION	<input type="checkbox"/>	DELETION
-------------------	--------------------------	---------------	-------------------------------------	-----------------	--------------------------	-----------------

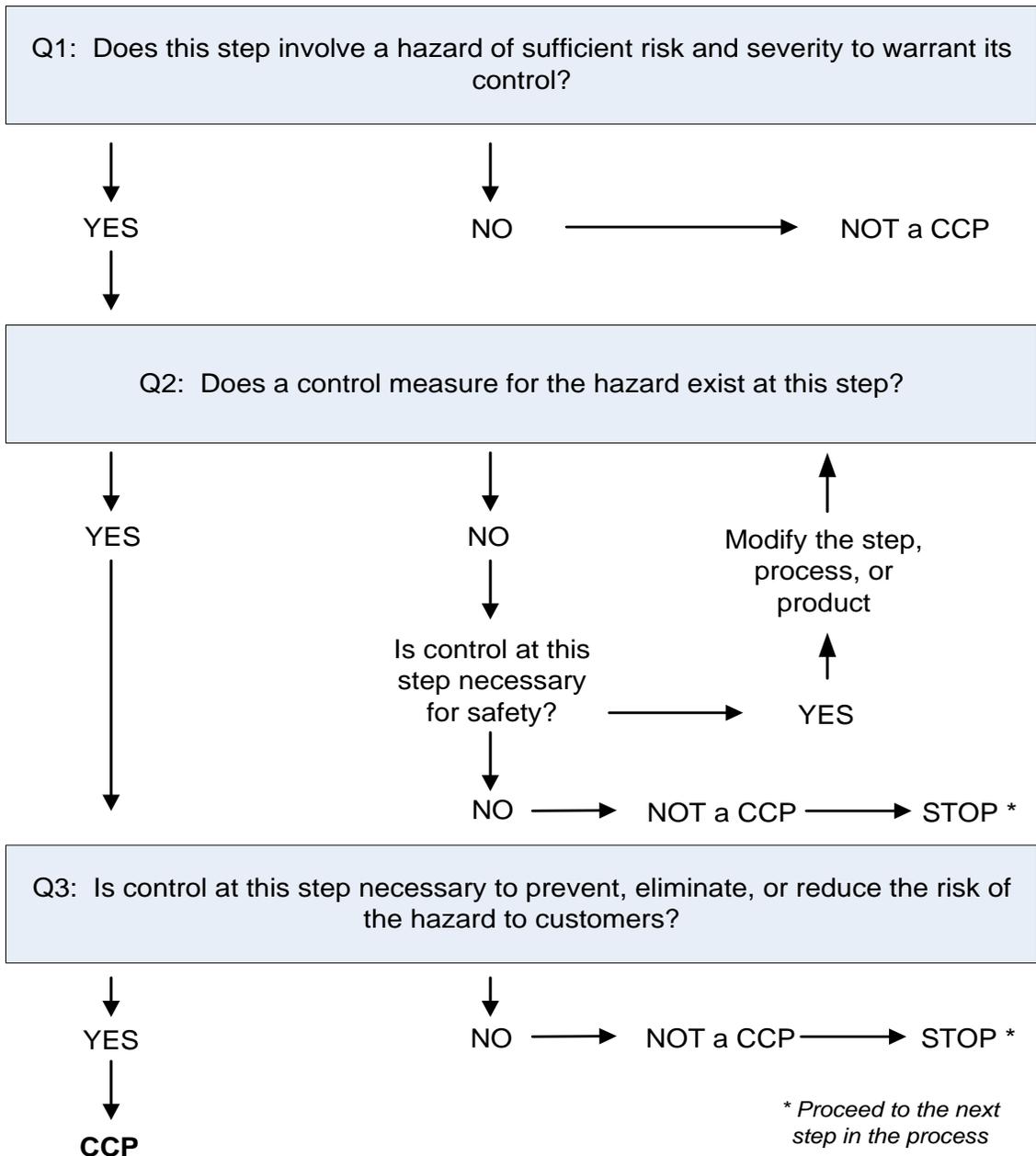
What specifically was Changed / Added / Deleted?
New ink supplier requiring all new compliance documents and trials for new ink to be completed.
Why was it Changed / Added / Deleted?
Corporate directive to use only this supplier. This is the new ink supplier for the entire company.
What is the basis for the Change / Addition / Deletion?
Forced to make the change and certify the new supplier by corporate initiatives.

Appendix A – 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



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 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.

U.S. Food and Drug Administration, Department of Health and Human Services, 2008. *Code of Federal Regulations*, Title 21 Food and Drugs Part 110, Washington, D.C.

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.