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: **Extrusion Lamination**

EXTLAM1 Revision 05-06-2010

Prepared by representatives of the following companies:

Alcan Packaging
Berry Plastics
Campbell Soup Company
ConAgra Foods
General Mills
Graham Packaging Company
Graphic Packaging

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

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.
e. It must be noted the Critical Control Points outlined in this model are only POTENTIAL CCPs. The plan may/will vary depending on your processes and programs.

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: StanLee Packaging, Marvel Facility		**Date**: *February 18, 20XX*	
Team Member Name	**Team Member Name**	**Team Member Name**	**Team Member Name**
C. Kent	*C. Kent*	*C. Kent*	*C. Kent*
D. Prince	*D. Prince*	*D. Prince*	*D. Prince*
S. Kyle	*S. Kyle*	*S. Kyle*	*S. Kyle*
B. Banner	*B. Banner*	*B. Banner*	*B. Banner*
P. Parker	*P. Parker*	*P. Parker*	*P. Parker*
B. Wayne	B. Wayne	B. Wayne	B. Wayne

Facility HACCP Charter

Facility Name: StanLee Packaging, Marvel Facility	Date: *February 18, 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	*C. Kent*
Management Representative	L. Jefe	*L. Jefe*
HACCP Team Member	D. Prince	*D. Prince*
HACCP Team Member	S. Kyle	*S. Kyle*
HACCP Team Member	B. Banner	*B. Banner*
HACCP Team Member	P. Parker	*P. Parker*
HACCP Team Member	B. Wayne	*B. Wayne*

Facility Training Log

Subject	*HACCP Hazard Analysis*
Date(s)	*July 15, 20XX*
Trainer's Name & Title	*C. Kent – Food Safety Manager*
Materials Used	*CCP Decision Tree, Internal SOPs*

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

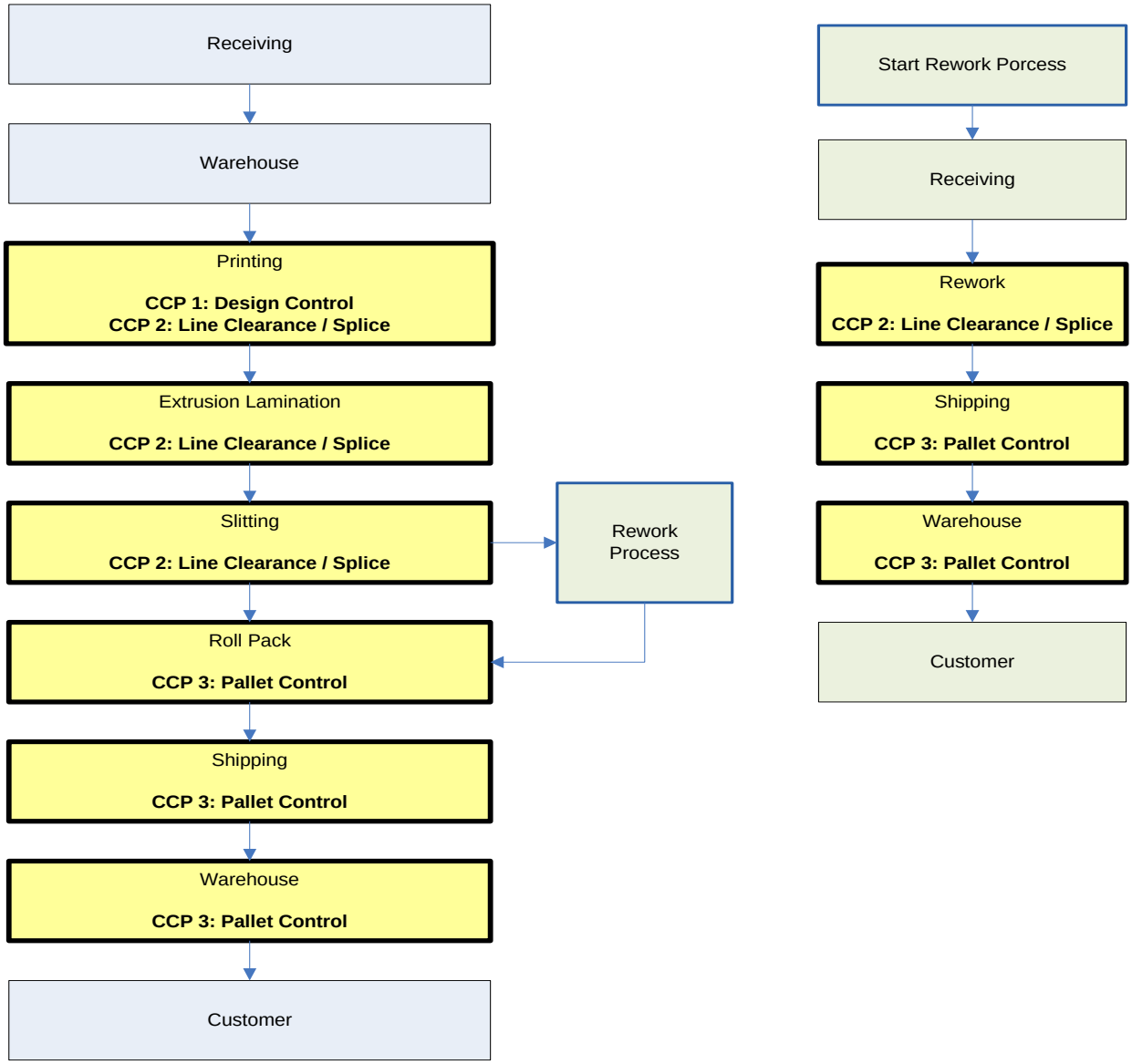
a. What do you make
b. How do you make it
c. Intended usage (include time and temperature as applicable)
d. What Raw Materials are used
e. Intended markets / customers
f. Document: Written Descriptions of what is made and production process

Product / Product Category Description

Facility Name: : *StanLee Packaging, Marvel Facility*	**Date**: *July 30, 20XX*
Product/Product Category	*Flexible Packaging Film – Multi-layer laminations*
Process	*Extrusion Lamination, Coating, etc of flexible packaging materials*
Food Safety Characteristics	*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.*
Customer Use	*Condiments, single serve beverages, dry foods, snacks*
Target Market/Consumer	*Food, Meat & Dairy, Healthcare markets. General Public*
General Raw Materials	*Supplied paper, films, foils, resins, primers and additives*
Packaging/Palletization	*Bagged, Palletized and Stretch wrapped*
Shelf Life	*1 year, TBD-Various*
Storage & Distribution	*-20°F – 120°F, protect from moisture*
Other	*None (in this example)*

13. 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



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

a. Team walks through plant with PFD
b. Confirm PFD with team and plant floor workers
c. Make necessary changes before proceeding
d. 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: *StanLee Packaging, Marvel Facility*	**Date**: *August 24, 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? 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.
Films	C: ---				
	P: *Foreign Material*	*Yes - Receiving Inspection*			
	B: ---				
Primers	C: *Plant Chemical*	*Yes – Chemical control plan*			
	P: *Foreign Material*	*Yes – GMP*			

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.
Resins	C: ---				
	P: *Mixed labels, Foreign Material*	*Yes - Design control, line clearance, GMP*			
	B: ---				
Foil	C: ---				
	P: *Mixed labels, Foreign Material*	*Yes - Design control, line clearance, GMP*			
	B: ---				
Inks	C: *Off-flavor/odor*	*Yes-Letters of guaranty from supplier.*			
	C: *Chemical Migration*	*Yes-Letters of guaranty from supplier.*			
	P: --				
	B: --				
Graphics Plates & Cylinders	C: Mixed labels	*No*	*No*	*Design Control*	*CCP 1*
	P: ---				
	B: ---				
Pallets & Packing Materials	C: --- *Off-odor*	*Yes, Specification to exclude using wood preservatives, incoming inspection*			
	P: Foreign Material	*Yes – GMP, Receiving inspection*			
	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.
	P: *Foreign Material (wood, nails, other)*	*Yes - GMPs, Incoming Material Inspection Program*			

Process Hazard Analysis

Facility Name: *StanLee Packaging, Marvel Facility*	**Date**: *August 24, 20XX*

1	2	3	4	5	6
List each process step from the Process Flow Diagram. Also, bring forward each ingredient from the Material Hazard Analysis Worksheet that was determined to be a Critical Ingredient.	Does this ingredient or process step 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.
Receiving	C: ---				
	P: *Foreign Material*	*Yes, Receiving Inspection*			
	B: ---				
Warehouse	C: ---				
	P: *Foreign Material*	*Yes – GMP*			
	B: ---				
Graphics Plates & Cylinders	C: Mixed labels	*No*	*No*	*Design Control*	*CCP 1*
	P: ---				
	B: ---				
Printing	C: *Mixed designs*	*No*	*No*	*Design Control* *Line Clearance - Splices*	*CCP 1* *CCP 2*
	C: *Off-flavor/odor*	*Yes-Process step: proper ink curing and solvent flashing-off, sniff test, and/or GC confirmation*			

1	2	3	4	5	6
List each process step from the Process Flow Diagram. Also, bring forward each ingredient from the Material Hazard Analysis Worksheet that was determined to be a Critical Ingredient.	Does this ingredient or process step 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*	*Yes-Process step: proper ink curing and solvent flashing-off, sniff test, and/or GC confirmation*			
	P: *Foreign Material*	*Yes – GMP*			
	B: ---				
Laminating	C: *Mixed Designs*	*No*	*No*	*Line Clearance - Splices*	*CCP 2*
	P: *Foreign Material*	*Yes – GMP*			
	B: ---				
Slitting	C: *Mixed Designs*	*No*	*No*	*Line Clearance - splices*	*CCP 2*
	P: *Foreign Material*	*Yes -GMP*			
	B: ---				
Roll Doctor	C: *Mixed Designs*	*No*	*No*	*Line Clearance - splices*	*CCP 2*
	P: *Foreign Material*	*Yes, GMP*			
	B: ---				
Roll Pack	C: *Mixed Designs Mixed labels*	*No*	*No*	*Pallet control*	*CCP 3*
	P: *Foreign Material*	*Yes., GMP*			
	B: ---				
Warehouse	C: *Mixed labels / boxes / rolls*	*No*	*No*	*Pallet Control*	*CCP 3*
	P: *Foreign Material*	*Yes, GMP*			
	B: ---				

1	2	3	4	5	6
List each process step from the Process Flow Diagram. Also, bring forward each ingredient from the Material Hazard Analysis Worksheet that was determined to be a Critical Ingredient.	Does this ingredient or process step 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.
Shipping	C: *Mixed labels / boxes / rolls*	*No*	*No*	*Pallet Control*	*CCP 3*
	P: *Foreign Material*	*Yes-Trailer Inspection, GMP*			
	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 HAACP 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: : *StanLee Packaging, Marvel Facility*	**Date**: *October 5, 20XX*
HACCP Plan Name / Number: *Extrusion Lamination / EXTLAM1*	

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. Incorrect Design	Incorrect material is printed in error	No incorrect printing is allowed.	Design segregation	Each design has a unique ID #.	Each order	Pre press	Segregate material and contact graphics supplier	Visual inspection of plate / cylinder to customer proof.	Graphics Receiving report
2. Line Clearance and Splice	Materials may be mixed or spliced together	No incorrect material is allowed	Line clearance and splice procedures	SOP for operators	Each order	Operator	Segregate material. Initiate recall if needed	Verified by co-worker	Job change over sheet
3. Pallet control	Ensure that rolls or labels are not mixed on a pallet	No incorrect material is allowed	Pallet clearance and segregation	SOP for operators	Each Pallet	Operator	Segregate material. Initiate recall if needed	Verified by co-worker	Pallet Tally Sheet

Approved By: (Signature, Title, and Date)	*C. Kent, Food Safety Manager, October 12, 20XX*

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:		*Extrusion Lamination / EXTLAM1 Oct. 12, 20XX*	

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: None		

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:* Dryer system change**		
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: ***Change made to dryer system on the extrusion laminator. No significant change to flow diagram. See comments on reassessment form.***		

HAZARD ANALYSIS: (Each step in the process flow diagram must be addressed)		
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		

IDENTIFICATION OF CRITICAL CONTROL POINTS:		
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**
Documentation on file to support selection of CCPs?	**Yes**	*No*
Comments: None		

ESTABLISHMENT OF CRITICAL LIMITS:		
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**
Documentation on file to support establishment of critical limits?	**Yes**	*No*
Comments: None		

MONITORING PROCEDURES:		
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**
Monitoring records are being filled out correctly?	**Yes**	*No*
Comments: None		

CORRECTIVE ACTION:		
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**
Corrective Action records are being filled out correctly?	**Yes**	*No*
Comments: None		

RECORD KEEPING PROCEDURES:		
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**
Accurate and current record keeping forms are being used?	**Yes**	*No*
Comments: None		

VERIFICATION PROCEDURES:		
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**
Documentation on file to support verification?	**Yes**	*No*
Comments: None		

Additional Comments or Observations:
No changes identified during this review. *D. Reyes, October 26, 20XX*

HACCP Plan Reassessment Change Form

HACCP PLAN REASSESSMENT CHANGE FORM

EXAMPLE

Facility Name:	: *StanLee Packaging, Marvel Facility*	**Person(s) Responsible:**	*W. Wiksell, D. Reyes*
HACCP Plan Name/Number and Date:		*Extrusion Lamination / EXTLAM1 Oct. 12, 20XX*	

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:	*X*	**CHANGE**		**ADDITION**		**DELETION**

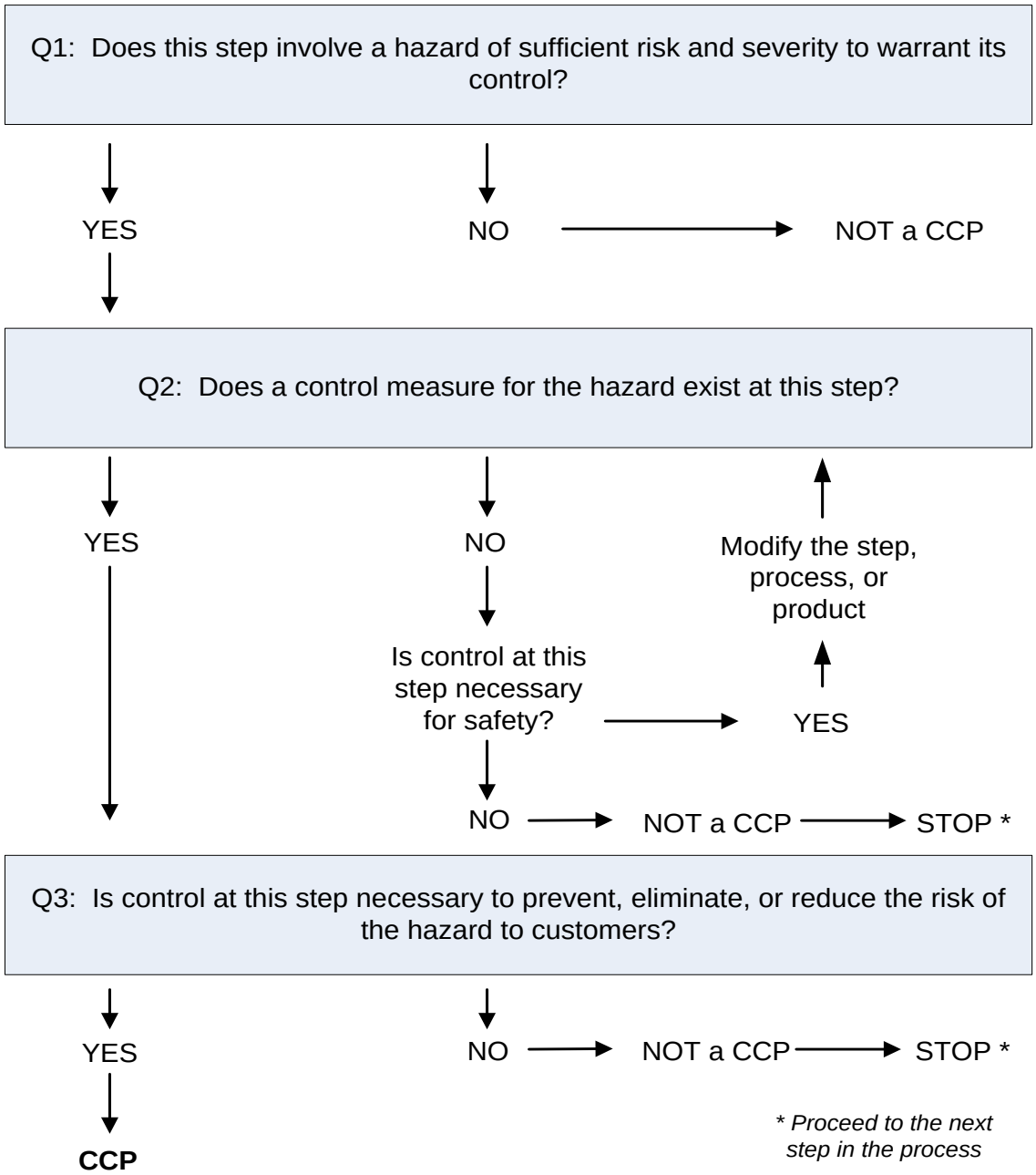
What specifically was Changed / Added / Deleted?
In mid 20XX, the facility replaced a dryer on the extrusion lamination line.
Why was it Changed / Added / Deleted?
The previous dryer system was more than +xx years old and was not capable of achieving temperatures of XXX ° F.
What is the basis for the Change / Addition / Deletion?
The above change does not impact the flow diagram or other aspects of the HACCP plan.

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



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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.

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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.

