

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

Packaging HACCP Plan Model: **Print, Adhesive Lamination & Slit**  
PRADLM1 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](http://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 – Print, Adhesive Lamination & Slit

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

<b>Facility Name:</b> <i>Adhesive Team</i>		<b>Date:</b> <i>June 30, 20XX</i>	
<b>Team Member Name</b>	<b>Department</b>	<b>Title</b>	<b>HACCP Team Role</b>
<i>D. Hand</i>	Food Safety	<i>Food Safety Manager</i>	<i>Coordinator</i>
<i>R. Jacobs</i>	Quality	<i>Quality Manager</i>	<i>Member</i>
<i>W. Wiksell</i>	Production	<i>Process Leader</i>	<i>Member</i>
<i>D. Reyes</i>	Maintenance	<i>CA/PA Leader</i>	<i>Member</i>
<i>W. Bowles</i>	Technical	<i>Engineer</i>	<i>Member</i>
<i>S. Matuszewski</i>	Customer Service	<i>CS Manager</i>	<i>Member</i>

## Facility HACCP Charter

**Facility Name:** *Adhesive Team*

**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	<i>D. Hand</i>	<i>D. Hand</i>
Management Representative	<i>T. White</i>	<i>T. White</i>
HACCP Team Member	<i>R. Jacobs</i>	<i>R. Jacobs</i>
HACCP Team Member	<i>W. Wiksell</i>	<i>W. Wiksell</i>
HACCP Team Member	<i>D. Reyes</i>	<i>D. Reyes</i>
HACCP Team Member	<i>W. Bowles</i>	<i>W. Bowles</i>
HACCP Team Member	<i>S. Matuszewski</i>	<i>S. Matuszewski</i>

## Facility Training Log

<b>Subject</b>	<i>HACCP Hazard Analysis</i>	
<b>Date(s)</b>	<i>July 15, 20XX</i>	
<b>Trainer's Name &amp; Title</b>	<i>D. Hand - Food Safety Manager</i>	
<b>Materials Used</b>	<i>CCP Decision Tree, Internal SOPs</i>	
<b>Print Name</b>	<b>Signature</b>	<b>Date</b>
<i>M. Steine</i>	<i>M. Steine</i>	<i>7/15/20XX</i>
<i>M. Nauman</i>	<i>M. Nauman</i>	<i>7/15/20XX</i>
<i>J. Wiley</i>	<i>J. Wiley</i>	<i>7/15/20XX</i>
<i>N. Soloman</i>	<i>N. Soloman</i>	<i>7/15/20XX</i>
<i>S. Cowell</i>	<i>S. Cowell</i>	<i>7/15/20XX</i>
<i>R. Jackson</i>	<i>R. Jackson</i>	<i>7/15/20XX</i>

## 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

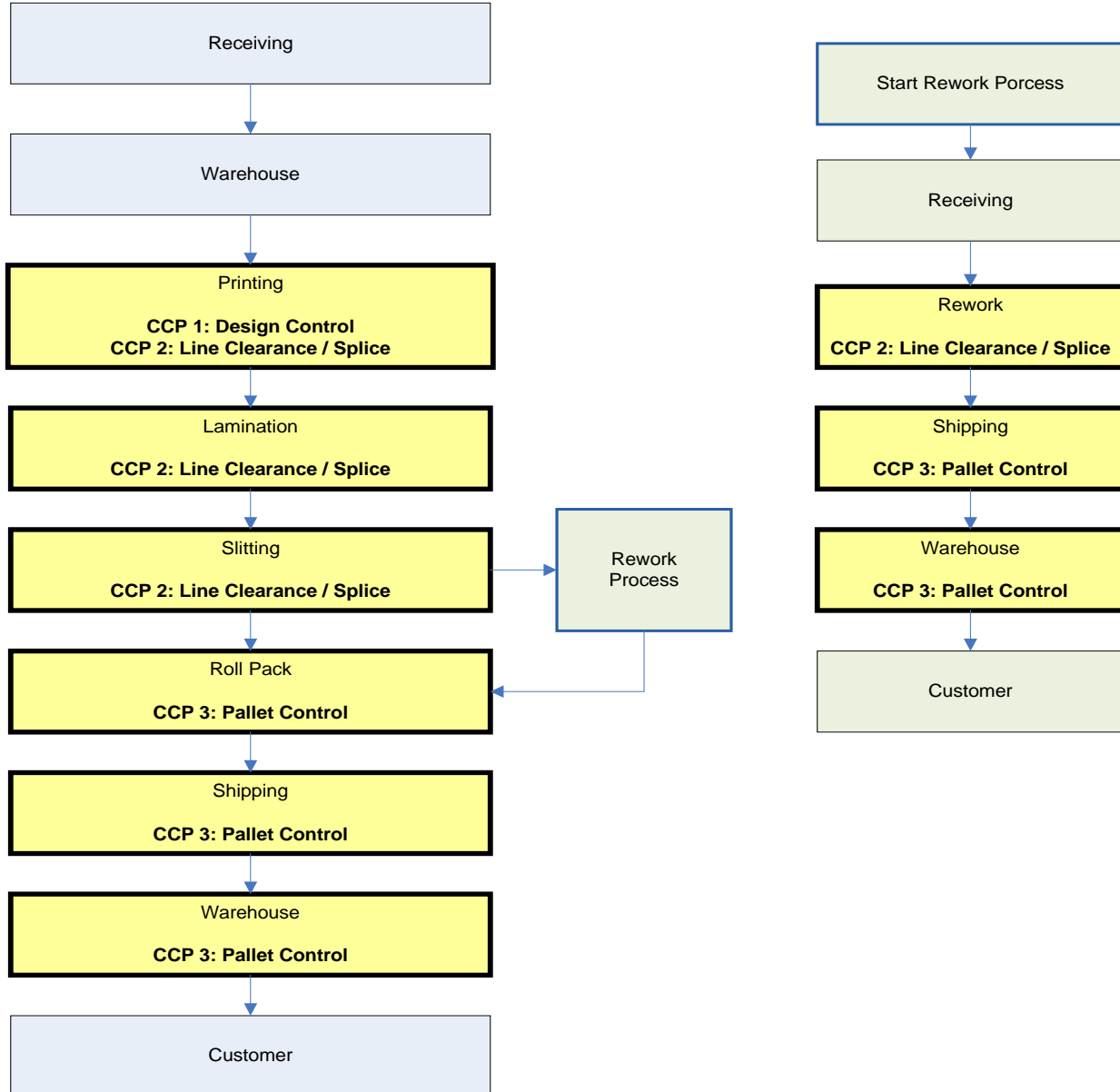
### Product / Product Category Description

<b>Facility Name:</b> <i>Adhesive Company</i>		<b>Date:</b> <i>July 30, 20XX</i>
<b>Product/Product Category</b>	<i>Flexible Packaging</i>	
<b>Process</b>	<i>Print/Adhesive Lamination/Slit of Flexible Packaging Material</i>	
<b>Food Safety Characteristics</b>	<i>Typically none. Possible issues with incorrect/mixed labeling</i>	
<b>Customer Use</b>	<i>Shredded cheese, snacks, confections</i>	
<b>Target Market/Consumer</b>	<i>Food, Meat &amp; Dairy, Healthcare markets. General Public</i>	
<b>General Raw Materials</b>	<i>Printed/unprinted Polymer films or paper, adhesive, sealant films, solvents, graphics, printing plates/cylinders</i>	
<b>Packaging/Palletization</b>	<i>Bagged, Palletized and Stretch wrapped</i>	
<b>Shelf Life</b>	<i>1 year, TBD-Variou</i>	
<b>Storage &amp; Distribution</b>	<i>-20 °F - 120 °F, protect from moisture</i>	
<b>Other</b>	<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

- 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. Chemical – Physical – Biological Hazards
- b. Evaluation of Raw Materials
- c. Evaluation of Processes
- d. Document: Hazard Analysis Sheets for Raw Materials and Processes

**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.

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

- a. Use CCP Decision Tree (See Appendix B)
- b. Confirm CCPs Using CCP Definition
- c. Document: Results Sheet for Decision Tree Responses
- d. Document: Product/Process Hazard Evaluation Summary

**Raw Material Hazard Analysis**

<b>Facility Name:</b> <i>Adhesive Company</i>	<b>Date:</b> <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.
<i>Films</i>	C: ---				
	P: <i>Foreign Material</i>	<i>Yes, Receiving Inspection</i>			
	B: ---				
<i>Adhesives</i>	C: <i>Plant Chemical</i>	<i>Yes - Chemical control plan</i>			
	P: <i>Foreign Material</i>	<i>Yes - GMP, Receiving inspection</i>			
	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.
<i>Inks</i>	C: Plant Chemical	<i>Yes - Chemical control plan</i>			
	P: ---				
	B: ---				
<i>Solvents</i>	C: Plant Chemical	<i>Yes - Chemical control plan</i>			
	P: ---				
	B: ---				
<i>Graphics Plates &amp; Cylinders</i>	C: Mixed labels	<i>No</i>	<i>No</i>	<i>Design Control</i>	<i>CCP 1</i>
	P: ---				
	B: ---				
<i>Pallets &amp; Packing Materials Graphics Plates &amp; Cylinders</i>	C: ---				
	P: Foreign Material	<i>Yes - GMP, Receiving inspection</i>			
	B: ---				
	C: Mixed labels	<i>No</i>	<i>No</i>	<i>Design Control</i>	<i>CCP 1</i>

## Process Hazard Analysis

<b>Facility Name:</b> <i>ADH Lamination Company</i>	<b>Date:</b> <i>August 24, 20XX</i>
---	-------------------------------------

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>
<b>Receiving</b>	C: ---				
	P: <i>Foreign Material</i>	<i>Yes, Receiving Inspection - GMP</i>			
	B: ---				
<b>Warehouse</b>	C: ---				
	P: <i>Foreign Material</i>	<i>Yes, Receiving Inspection - GMP</i>			
	B: <i>None</i>				
<b>Printing</b>	C: <i>Mixed designs</i>	<i>No</i>	<i>No</i>	<i>Design Control Line Clearance - Splices</i>	<i>CCP 1 CCP 2</i>
	P: <i>Foreign Material</i>	<i>Yes - GMP</i>			
	B: ---				
<b>Laminating</b>	C: <i>Mixed Designs</i>	<i>No</i>	<i>No</i>	<i>Line Clearance - Splices</i>	<i>CCP 2</i>
	P: <i>Foreign Material</i>	<i>Yes - GMP</i>			
	B: ---				
<b>Slitting</b>	C: <i>Mixed Designs</i>	<i>No</i>	<i>No</i>	<i>Line Clearance - splices</i>	<i>CCP 2</i>
	P: <i>Foreign Material</i>	<i>Yes - GMP</i>			
	B: ---				
<b>Roll Doctor</b>	C: <i>Mixed Designs</i>	<i>No</i>	<i>No</i>	<i>Line Clearance - splices</i>	<i>CCP 2</i>

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>
	<p>P: <i>Foreign Material</i></p> <p>B: ---</p>	<p><i>Yes, GMP</i></p>			
<b>Roll Pack</b>	<p>C: <i>Mixed Designs Mixed labels</i></p>	<p><i>No</i></p>	<p><i>No</i></p>	<p><i>Pallet control</i></p>	<p><i>CCP 3</i></p>
	<p>P: <i>Foreign Material</i></p>	<p><i>Yes, GMP</i></p>			
	<p>B: ---</p>				
<b>Warehouse</b>	<p>C: <i>Mixed labels</i></p>	<p><i>No</i></p>	<p><i>No</i></p>	<p><i>Pallet Control</i></p>	<p><i>CCP 3</i></p>
	<p>P: <i>Foreign Material</i></p>	<p><i>Yes, GMP</i></p>			
	<p>B: -</p>				
<b>Shipping</b>	<p>C: <i>Mixed labels</i></p>	<p><i>No</i></p>	<p><i>No</i></p>	<p><i>Pallet Control</i></p>	<p><i>CCP 3</i></p>
	<p>P: <i>Foreign Material</i></p>	<p><i>Trailer Inspection, GMP</i></p>			
	<p>C: <i>Mixed Designs</i></p>	<p><i>No</i></p>	<p><i>No</i></p>	<p><i>Line Clearance - splices</i></p>	<p><i>CCP 2</i></p>

**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:** *Adhesive Company*

**Date:** *October 5, 20XX*

**HACCP Plan Name / Number:** *Print, Adhesive Lamination & Slit / PRADLM1*

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			
<b>1. Incorrect Design</b>	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
<b>2. Line Clearance and Splice</b>	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
<b>3. Pallet control</b>	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)**

*D. Hand, 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](http://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.

<b>Facility Name:</b>	Adhesive Company	<b>Person(s) Responsible:</b>	W. Wiksell, D. Reyes
<b>HACCP Plan Name/Number and Date:</b>	Print, Adhesive Lamination & Slit / PRADLM1 Oct. 12, 20XX		

<b>PRODUCT DESCRIPTION(s):</b>		
Reassessor(s): W. Wiksell, D. Reyes	Date: October 26, 20XX	
Changes Needed? (Choose Yes or No)	Yes	<b>No</b>
HACCP Plan Reassessment Change Form Completed?	Yes	<b>No</b>
Comments: None		

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

<b>PROCESS FLOW DIAGRAM: Dryer system change</b>		
Reassessor(s): W. Wiksell, D. Reyes	Date: October 26, 20XX	
Changes Needed? (Choose Yes or No)	<b>Yes</b>	No
HACCP Plan Reassessment Change Form Completed?	<b>Yes</b>	No
Comments: <i>Change made to dryer system on the adhesive laminator. No significant change to flow diagram. See comments on reassessment form.</i>		

<b>HAZARD ANALYSIS: (Each step in the process flow diagram must be addressed)</b>
---

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

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

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

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

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

Corrective Action records are being filled out correctly?	<b>Yes</b>	<i>No</i>
Comments: None		

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

<b>VERIFICATION PROCEDURES:</b>		
Reassessor(s): <i>W. Wiksell, D. Reyes</i>	Date: <i>October 26, 20XX</i>	
Changes Needed? (Choose Yes or No)	<i>Yes</i>	<b>No</b>
HACCP Plan Reassessment Change Form Completed?	<i>Yes</i>	<b>No</b>
Documentation on file to support verification?	<b>Yes</b>	<i>No</i>
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*

<b>Facility Name:</b>	<i>Adhesive Company</i>	<b>Person(s) Responsible:</b>	<i>W. Wiksell, D. Reyes</i>
<b>HACCP Plan Name/Number and Date:</b>	<i>Print, Adhesive Lamination &amp; Slit / PRADLM1 Oct. 12, 20XX</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.

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

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

# Appendices

## Appendix A – Prerequisite Programs

- 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. The program should encompass a wide range of food safety procedures related to the products manufactured in the facility. See also U.S. Code of Federal Regulations 21CFR110.

The program should include, but not be limited to:

- a. An assigned person/position responsible for managing the program
  - b. A GMP/Quality Manual which includes
    - i. Personnel Requirements / Hygiene
    - ii. Shipping and Storage
    - iii. Maintenance
    - iv. Operations Practices
    - v. Employee Practices
    - vi. Facility and Grounds expectations
  - c. Lot Traceability and Recall information
  - d. Allergen Awareness
  - e. Food Defense
  - f. Documentation Practices
  - g. Location Specific GMP/Quality Topics
- 2) Cleaning/Sanitation Program: Cleaning/sanitation will vary based upon the products and processes at the facility. 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. The program should include:
    - a. An assigned person/position responsible for managing the program
    - b. Detailed cleaning and sanitizing instructions (including chemical and concentration)
    - c. Approved cleaning/sanitizing chemical list
    - d. Cleaning schedule (daily, weekly, monthly, yearly)
    - e. Documented training
  - 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. This program should complement your Hazard Communication Program. Compliance shall be accomplished through a Chemical Control Program which manages the purchase, receiving, storage, mixing, labeling and use of all chemicals used in the plant. The program should include:
    - a. An assigned person/position responsible for managing the program
    - b. Approved Chemical List
    - c. Chemical Storage Areas: locked, segregated, controlled
    - d. MSDS
    - e. Training
    - f. Hazardous Communication / Emergency Procedures
    - g. Chemical Inventory
  - 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 non-replaceable glass, brittle plastic, or ceramic objects should be used as part of the audit. Objects on this list include computer monitors on the floor, lab equipment, and structural glass (windows to offices). Objects that should be either on the list or replaced with shatterproof versions can include, but are not limited to: gauges; lights; doors; thermometers; alarms/alarm covers; light bulbs; dock lights; lab equipment (if in-line and not isolated).

- 5) Pest Control: The goal of the Pest Control Program is to exclude pests from the plant (i.e., 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. The pest control program assists the plant in maintaining a pest-free environment.

The program should include:

- a. An assigned person/position responsible for managing the program
- b. Pest Control Policy
- c. Licensed & Insured Pest Control Company (unless handled internally)
- d. Internal and External device monitoring logs; trend charts
- e. Utilization of approved chemicals and bait
- f. Sighting & catch logs
- g. MSDS and sample labels
- h. Pesticides stored off site (preferred)
- i. Internal verification
- j. Food Safety/GMP training for the PCO

- 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. Good record keeping practices shall be followed.

The document control program ensures current and accurate information is distributed via documentation throughout the plant. A document control policy shall be in place and audited. Document retention times shall be defined.

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

The program should include:

- a. An assigned person/position responsible for managing the program
- b. Tracking of equipment undergoing maintenance and temporary repairs
- c. Preventive maintenance schedule with frequencies and verification
- d. A tools and parts control program
- e. Post-maintenance inspection procedures
- f. Documentation requirements

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

The program should include:

- a. An assigned person/position responsible for managing the program
- b. MSDS policy
- c. MSDS availability for employees

- 9) Allergen Awareness / Management: Allergen Control Programs shall include employee training on allergen awareness as well as on specific areas based on the type of packaging material being produced. Posted reminders and visual aids to promote continued awareness

may be helpful to reinforce the importance of allergen controls. The program shall also include an assigned person/position responsible for managing the program.

This prerequisite program should consider 3 areas of allergen uses in the plant:

- a. Packaging printing/artwork control (prevent potential mislabeling of foods)
- b. Raw Materials that are allergenic (e.g., wheat, soy)
- c. Allergen presence in lunchrooms, offices, and designated areas.

These programs should include:

- i. Packaging printing/artwork control
  1. As assigned—verification that print copy matches customer proof copy
  2. Layout of copy to prevent potential for materials to be mixed after printing/cutting/stacking
  3. Control of printing plates, cylinders, and blankets to prevent use of obsolete or incorrect media
  4. Control of materials within the manufacturing process to prevent mixing of materials within a box, roll, skid, pallet, etc.
- ii. Raw Materials used in or on packaging (including processing aids)
  1. As assigned (e.g., wheat flour as a release agent)
  2. Cleaning/sanitizing (visual inspection and/or testing)
- iii. Allergen presence in the facility
  1. Vending Machines (e.g., peanuts)
  2. Employee lunches

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

The program should include:

- a. An assigned person/position responsible for managing the program
- b. Testing and quality checks at pre-determined frequencies
- c. Line clearance procedures for start-up and changeovers
- d. Employee training program
- e. Quality documentation completed and reviewed daily by quality or operations personnel

11) Line Clearance: All labels, packing material, 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 bringing materials for the next job to the work area.

- a. An assigned person/position responsible for managing the program
- b. The line clearance shall be documented. A secondary inspection is recommended.
- c. Line clearance records shall be retained following existing company policy.

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. Lot traceability must be maintained.

The program should include:

- a. An assigned person/position responsible for managing the program
- b. Lot information
- c. Inventory/shipment records

- d. Recall and notification procedures including contact information for the leader and team members
  - e. Action plans
  - f. Product disposition guidelines
  - g. Hold area/procedures
  - h. Contact information for customers and regulatory agencies
- 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:
- a. An assigned person/position responsible for managing the program
  - b. A written procedure and audit check sheet
  - c. The audit frequency
  - d. A written report and documented corrective actions
  - e. Key performance indicators for the plant.
- 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. The program should include:
- a. An assigned person/position responsible for managing the program
  - b. Customer Complaint Procedure
  - c. Identification of Food Safety versus Quality issues
  - d. Root Cause Analysis
  - e. Follow-up and Corrective Action plan
  - f. Responding to the Customer
  - g. Disposition of Product
- 15) Certificates of Analysis (COA)/Certificate of Conformance (COC): The facility will maintain a Certificate of Analysis/Conformance program. The facility should not allow chemicals, raw materials, or label material to be used in the process without being accompanied by a COA or COC. The program should include:
- a. An assigned person/position responsible for maintaining the COAs/COCs
  - b. A procedure addressing missing documentation, i.e., how to obtain the documentation, what to do with materials prior to receipt of a COA, and responsibilities and expectation timeframes for your supplier.
- 16) Letters of Guarantee (LOG): The facility will maintain a Letter of Guarantee program. The facility should not allow chemicals, raw materials, or label material to be used in the process without being accompanied by a LOG, COA, or COC. The program should include:
- a. An assigned person/position responsible for maintaining the LOGs
  - b. A procedure addressing missing documentation, i.e., how to obtain the documentation, yearly submission requirements for LOGs, etc.
- 17) Microbiological Control: Microbiological testing requirements will vary based upon products, processes, government, and industry requirements. 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 aeruginosa* 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, analysis value with units, control result, acceptance limits (if established).

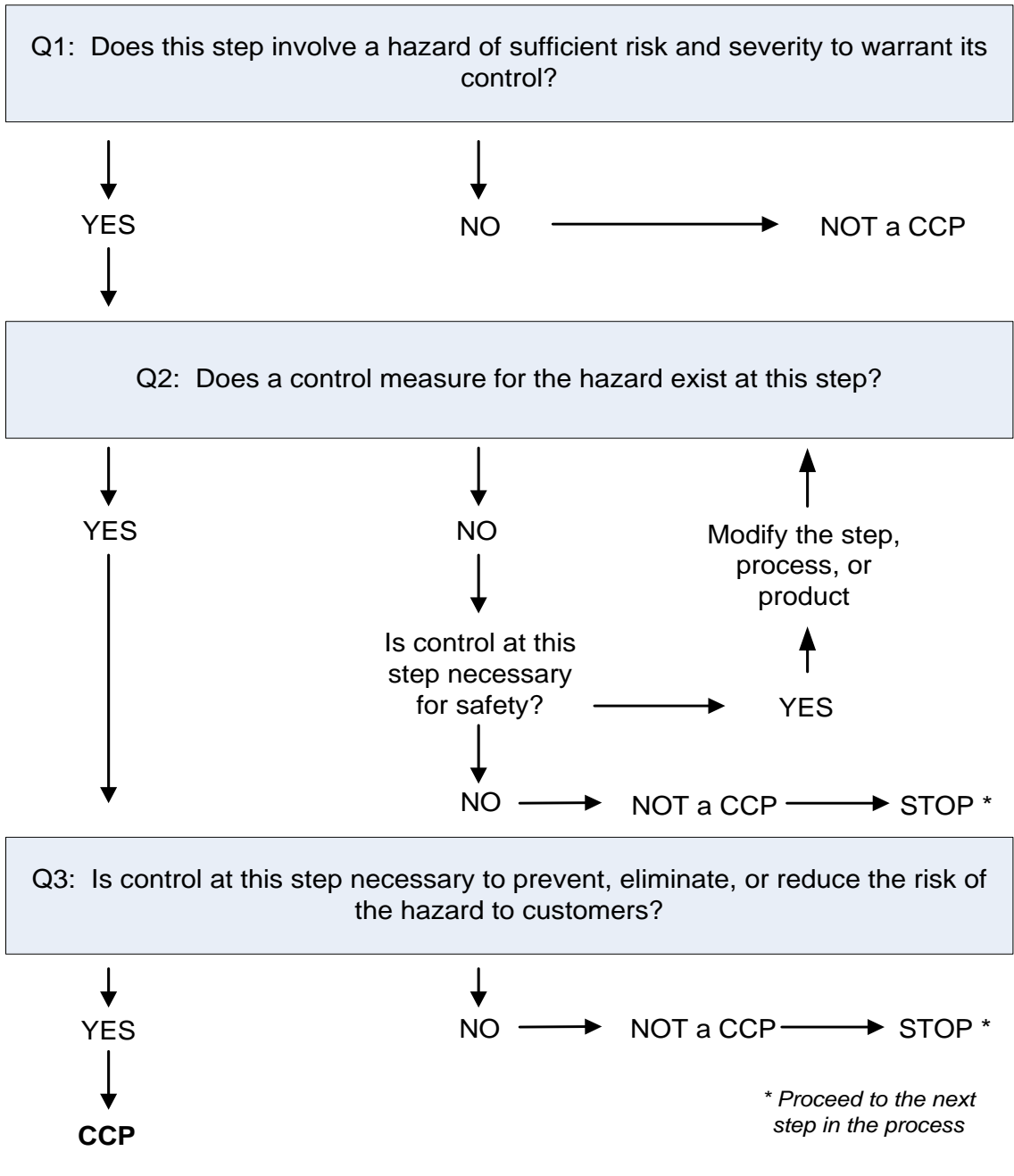
- 18) Packaging Security: The supplier shall have security systems in place to ensure the security of the workplace and products. Packaging Security audits shall occur at least yearly and when there are major changes to the building or equipment. Obsolete/unused printed packaging materials shall be disposed of properly (i.e., deface, destroy, slit, shred, etc.)

## 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 – Alternate Processing Step Evaluation / Hazard Analysis

### Sample Processing Step Evaluation / Hazard Analysis

<b>Facility Name:</b> <i>Adhesive Company</i>	<b>Date:</b> <i>August 24, 20XX</i>
---	-------------------------------------

PROCESSING STEP	BIOLOGICAL HAZARD VP=Vegetative Pathogens SP=Sporeforming Pathogens (Specify organism)	BIOLOGICAL HAZARD CCP	CHEMICAL HAZARD (Allergens, Sulphites, Pesticides, Heavy Metals, Chemicals not approved for direct or indirect food contact))	CHEMICAL HAZARD CCP	PHYSICAL HAZARD Inherent to equipment or environment. (Metal, Glass, Hard Plastic)	PHYSICAL HAZARD CCP
<b>MATERIAL RECEIVING AND STORAGE</b>						
<i>Raw Material Receiving (paper, Film, corrugate, slipsheets, banding, stretch wrap, etc.)</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>
<i>Storage of Raw Materials in Warehouse</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>
<b>PRINTING OPERATION</b>						
<i>Flexo, Roto, litho, or other printing method. Print verified design on substrate. Verification of copy and design # to customer proof. Segregate orders</i>	<i>None</i>	<i>None</i>	<i>YES - Allergen - potential for mislabeling if materials are mixed. Design control (CCP 1 &amp; splices line-clearance CCP 2)</i>	<i>CCP 1 &amp; CCP 2</i>	<i>None</i>	<i>None</i>
<b>LAMINATING OPERATION</b>						
<i>Laminate printed/unprinted material to sealant, foil or other films</i>	<i>None</i>	<i>None</i>	<i>YES - Allergen - potential for mislabeling if materials are mixed.</i>	<i>CCP 2</i>	<i>None</i>	<i>None</i>
<b>SLITTING OPERATION</b>						
<i>Slit rolls to designated footage and width.</i>	<i>None</i>	<i>None</i>	<i>YES - Allergen - potential for mislabeling if materials are mixed.</i>	<i>CCP 2</i>	<i>None</i>	<i>None</i>
<b>ROLL DOCTOR – REPAIR/REWORK</b>						
<i>Repair rolls with quality defects, roll winding issues for shipment</i>	<i>None</i>	<i>None</i>	<i>YES - Allergen - potential for mislabeling if materials or roll labels are</i>	<i>CCP 2</i>	<i>None</i>	<i>None</i>

			<i>mixed.</i>			
<b>ROLL PACK - SHIPPING</b>						
<i>Pack rolls per specification and prepare for shipment</i>	<i>None</i>	<i>None</i>	<i>YES - Allergen - potential for mislabeling if materials or pallet labels are mixed.</i>	<b>CCP 3</b>	<i>None</i>	<i>None</i>
<b>WAREHOUSE – SHIPPING</b>						
<i>Pull pallets and rolls per customer order and ship</i>	<i>None</i>	<i>None</i>	<i>YES - Allergen - potential for mislabeling if materials or pallet labels are mixed.</i>	<b>CCP 3</b>	<i>None</i>	<i>None</i>

# Appendix D – Alternate Product / Process Hazard Evaluation Summary

## Product / Process Hazard Evaluation Summary

**PURPOSE:** Provides a summary of identified hazards, control mechanisms, identification of the CCP (s), and an overview of hazard management.

<b>Facility Name:</b> <i>Adhesive Company</i>	<b>Date:</b> <i>September 21, 20XX</i>
<b>HACCP Plan Name / Number:</b> <i>Print, Adhesive Lamination &amp; Slit / PRADLM1 Oct. 12, 20XX</i>	

HAZARD IDENTIFIED	CONTROL MECHANISM (S)	If the hazard is managed as a CCP, list CCP	If the hazard is managed as a Prerequisite Program (PP), list the Prerequisite Program name.
<b><i>BIOLOGICAL</i></b>			
<i>None</i>			

HAZARD IDENTIFIED	CONTROL MECHANISM (S)	If the hazard is managed as a CCP, list CCP	If the hazard is managed as a Prerequisite Program (PP), list the Prerequisite Program name.
<b><i>CHEMICAL</i></b>			
<i>Heavy Metals (inks and coatings)</i>	<i>Supplier Guarantee, COC</i>		<i>Supplier Guarantee, COC</i>
<i>Allergen (print error due to mixed plate error-- potential for unlabeled allergen)</i>		<b><i>CCP 1</i></b>	
<i>Allergen— Printing (potential mixing of material within a roll)</i>		<b><i>CCP 2</i></b>	
<i>Allergen— Laminating (potential mixing of material within a roll)</i>		<b><i>CCP 2</i></b>	
<i>Allergen— Slitting (potential mixing of material within a roll, pallet)</i>		<b><i>CCP 2</i></b>	
<i>Allergen— Roll Pack - Pack rolls on the correct pallet. No mixing of material.</i>		<b><i>CCP 3</i></b>	
<i>Allergen— Warehouse-Shipping - Ship correct</i>		<b><i>CCP 3</i></b>	

<i>rolls with correct labeling</i>			
------------------------------------	--	--	--

HAZARD IDENTIFIED	CONTROL MECHANISM(S)	If the hazard is managed as a CCP, list CCP	If the hazard is managed as a Prerequisite Program, list the Prerequisite Program name.
<b>PHYSICAL</b>			
<i>Wood Splinters, Nails, Other Extraneous Materials from Wooden Pallets</i>	<i>Incoming inspection, GMP</i>		<i>Incoming inspection, GMP</i>

## 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.