

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

Packaging HACCP Plan Model: **Rigid Plastics**
RDGPLA1 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
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- 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 – Rigid Plastic

- a. This model should be used for any Rigid Plastic 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 (Wite-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: *Rigid HACCP Team*

Date: *June 30, 20XX*

Team Member Name	Department	Title	HACCP Team Role
<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: *Rigid HACCP 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

Subject	<i>HACCP Hazard Analysis</i>	
Date(s)	<i>July 15, 20XX</i>	
Trainer's Name & Title	<i>D. Hand - Food Safety Manager</i>	
Materials Used	<i>CCP Decision Tree, Internal SOPs</i>	
Print Name	Signature	Date
<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

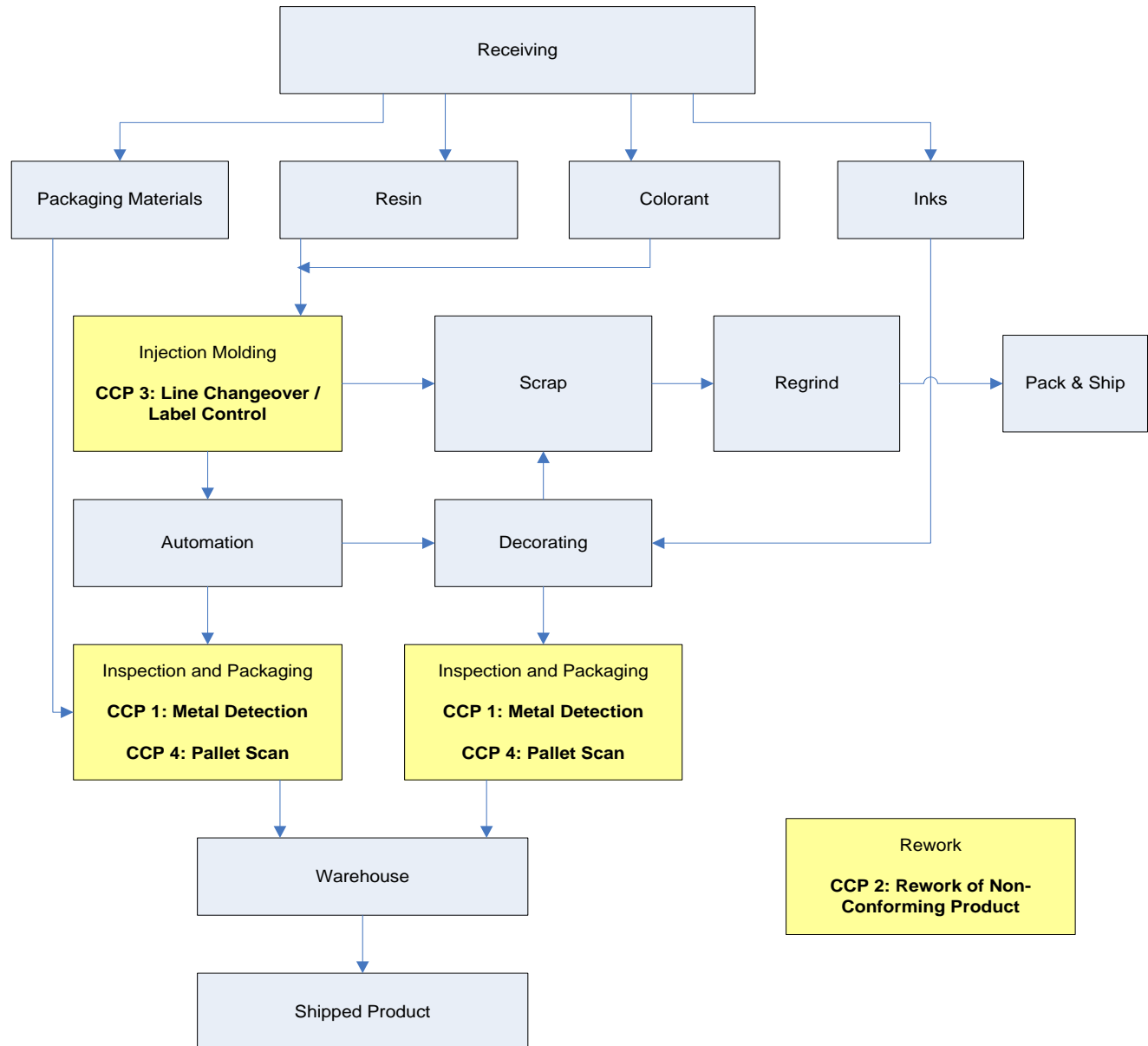
- What do you make
- How do you make it
- Intended usage (include time and temperature as applicable)
- What Raw Materials are used
- Intended markets / customers
- Document: Written Descriptions of what is made and production process

Product / Product Category Description

Facility Name: <i>Rigid Plastic Company</i>		Date: <i>July 30, 20XX</i>
Product/Product Category	<i>Rigid Plastic Containers and Lids to be used for a variety of food and beverage companies.</i>	
Food Safety Characteristics	<i>Direct and Indirect Food Contact. Printing and labeling 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. Measure must also be instituted for the prevention of foreign objects such as metal contamination.</i>	
Customer Use	<i>Direct and Indirect food and non food packaging such as Dairy (Sour Cream, Cottage Cheese, Deserts), Pasta, Ice Cream, etc.</i>	
Target Market/Consumer	<i>Products are supplied to Food Companies for packing to be sold to the consumer and grocery stores etc.</i>	
General Raw Materials	<i>Variety of plastics, printing inks, plastic storage bags and corrugates.</i>	
Packaging/Palletization	<i>Products are placed inside a poly bag, then into a cardboard box. Placed on a pallet in a variety of quantities, sizes and configurations dependant on customer requirements.</i>	
Shelf Life	<i>Typically 2 years dependant on storage and handling conditions</i>	
Storage & Distribution	<i>Stored in warehouses, internally, externally and at the end user. Conditions should be dry, ambient and clean, before being filled at the customer and then typically in refrigerated conditions before moving onto the consumer.</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

- 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

Facility Name: <i>Rigid Plastic Company</i>	Date: <i>August 24, 20XX</i>
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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.
Resin	C: ---				
	P: <i>Foreign Material</i>	<i>Yes - PP: Letter of Guarantee</i>			
	B: ---				
Colorant	C: ---				
	P: <i>Foreign Material</i>	<i>Yes - PP: Letter of Guarantee</i>			
	B: ---				
Antistat	C: ---				
	P: ---				

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.
	B: ---				
Inks	C: Heavy Metals	Yes - PP: Heavy Metals Warranty From Supplier			
	P: ---				
	B: ---				
Poly Bag	C: ---				
	P: Foreign Material	Yes - PP: COA From Supplier, Product Inspections			
	B: --				
Corrugated Cases	C: ---				
	P: ---				
	B: ---				
Tape	C: ---				
	P: ---				
	B: ---				
Slip Sheets (Cardboard)	C: ---				
	P: ---				
	B: ---				
Pallets	C: ---				
	P: Foreign Material	Yes - PP: Incoming Inspection for Foreign Material			
	B: ---				
Stretch Wrap Film	C: ---				
	P: ---				
	B: ---				

Process Hazard Analysis

Facility Name: <i>Rigid Plastic Company</i>	Date: <i>August 24, 20XX</i>
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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 / Warehouse	C: ---				
	P: <i>Foreign Material</i>	<i>Yes - PP: Incoming Inspection</i>			
	B: ---				
Injection Molding	C: <i>Allergen</i>	<i>No</i>	<i>No</i>	<i>Line Changeover and Label Control</i>	<i>CCP 3</i>
	P: <i>Metal</i>	<i>Yes - PP: Screens, Magnets</i>			
	B: ---				
Automation	C: ---				
	P: ---				
	B: ---				
Packaging	C: ---				
	P: <i>Metal</i>	<i>No</i>	<i>No</i>	<i>Case Metal Detection</i>	<i>CCP 1</i>
	B: ---				
Warehouse	C: ---				
	P: <i>Mixed Skids</i>	<i>No</i>	<i>No</i>	<i>Pallet Scan</i>	<i>CCP 4</i>
	B: ---				
Printing / Decorating	C: <i>Allergen due to mislabeling</i>	<i>No</i>	<i>No</i>	<i>Line Changeover and Label Control</i>	<i>CCP 3</i>
	P: ---				
	B: ---				
Packaging	C: ---				
	P: <i>Metal</i>	<i>No</i>	<i>No</i>	<i>Case Metal Detection</i>	<i>CCP 1</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>
	B: ---				
Warehouse	C: ---				
	P: <i>Mixed Skids</i>	<i>No</i>	<i>No</i>	<i>Pallet Scan</i>	<i>CCP 4</i>
	B: ---				
Shipping	C: ---				
	P: ---				
	B: ---				
Rework	C: <i>Allergen</i>	<i>No</i>	<i>No</i>	<i>Rework Controls</i>	<i>CCP 2</i>
	P: ---				
	B: ---				

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>Rigid Plastic Company</i>	Date: <i>October 5, 20XX</i>
HACCP Plan Name / Number: <i>Rigid Plastic / RDGPLA1</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			
<i>1: Metal Detection</i>	<i>Metal contamination in finished product.</i>	<i>Zero metal contamination For Cases: Ferrous: 3.0 mm Non-ferrous: 3.5 mm Stainless: 5.0 mm (Example sizes ; location & aperture dependent)</i>	<i>Metal Detector</i>	<i>Each case passes through detector</i>	<i>Each case</i>	<i>Operator</i>	<i>Cases kicked off and then inspected</i>	<i>Each case is run through and metal detector is validated every shift</i>	<i>Metal Detector Logs</i>
<i>2: Rework of Product</i>	<i>Potential for mixed product during rework operation</i>	<i>Zero Mixed Cases</i>	<i>Procedure detailing process</i>	<i>Operator follows procedure</i>	<i>Any product in rework</i>	<i>Inspector</i>	<i>Corrective Actions implemented</i>	<i>Random Quality audits</i>	<i>Rework logs</i>
<i>3: Line Changeover /Label Control</i>	<i>Allergen potential for mixed product in a box and mislabeled product</i>	<i>Zero Mixed products in a box and Mislabeled boxes</i>	<i>Each changeover and every box</i>	<i>Each step is verified and then co-signed</i>	<i>Each changeover and every box</i>	<i>Operator, technician and Quality Assurance</i>	<i>Stop process, place all cases on hold to last acceptable checks</i>	<i>Co-signed and end of changeover, label control log</i>	<i>Changeover log and label control log.</i>
<i>4: Mixed Skids</i>	<i>Allergen Potential for more then one product on a skid</i>	<i>Zero Mixed Skids</i>	<i>Pallet Scanning equipment</i>	<i>Verification of scanner with false label</i>	<i>Two times per shift</i>	<i>Quality Department</i>	<i>Process stops. Pallet is removed and inspected and then rescanned.</i>	<i>Shift Reviews of scanner logs</i>	<i>Scanning Logs</i>

Approved By: (Signature, Title, and Date)	<i>D. Hand, Food Safety Manager, October 12, 20XX</i>
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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:	Rigid Plastic Company	Person(s) Responsible:	W. Wiksell, D. Reyes
HACCP Plan Name/Number and Date:	Rigid Plastic / RDGPLA1		

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: Removal of older Injection molding machine		
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: <i>Injection Molding machine on line 3 has been taken out of service and will not be replaced. The process flow diagram does not change.</i>		

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? (<i>Choose Yes or No</i>)	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? (<i>Choose Yes or No</i>)	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? (<i>Choose Yes or No</i>)	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? (<i>Choose Yes or No</i>)	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? (<i>Choose Yes or No</i>)	Yes	No
HACCP Plan Reassessment Change Form Completed?	Yes	No

Corrective Action records are being filled out correctly?	Yes	<i>No</i>
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)	<i>Yes</i>	No
HACCP Plan Reassessment Change Form Completed?	<i>Yes</i>	No
Accurate and current record keeping forms are being used?	Yes	<i>No</i>
Comments: None		

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

Additional Comments or Observations: No changes identified during this review. <i>D. Reyes, October 26, 20XX</i>
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HACCP Plan Reassessment Change Form

HACCP PLAN REASSESSMENT CHANGE FORM

EXAMPLE

Facility Name:	<i>Rigid Plastic Facility</i>	Person(s) Responsible:	<i>W. Wiksell, D. Reyes</i>
HACCP Plan Name/Number and Date:	<i>Rigid Plastic / RDGPLA1</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 checked="" type="checkbox"/>	CHANGE	<input type="checkbox"/>	ADDITION	<input type="checkbox"/>	DELETION
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What specifically was Changed / Added / Deleted?
<i>Removal of older injection molding machine</i>
<i>The Injection Molding machine on line 3 has been removed and will not be replaced. The process flow diagram is not affected.</i>
Why was it Changed / Added / Deleted?
<i>Newer machines on lines 4 and 5 run at greater efficiencies. Excessive down time on line 3 led to the machine being taken out of service. It may be sold at auction.</i>
What is the basis for the Change / Addition / Deletion?
<i>Removing the machine on line 3 will allow the plant to improve overall performance. Food Safety and Quality will not be affected by this change.</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).

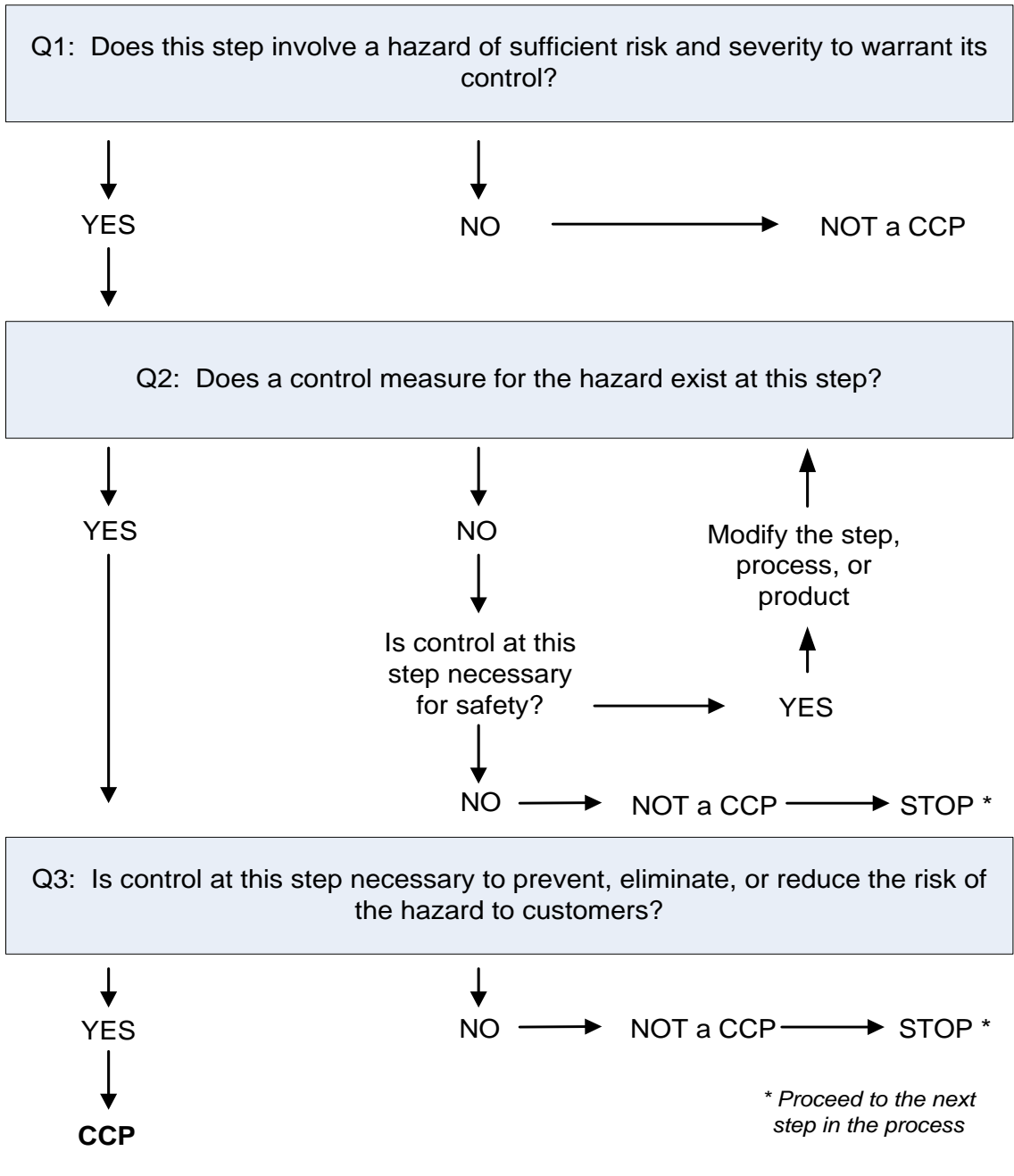
- 18) Packaging Security: The supplier shall have security systems in place to ensure the security of the workplace and products. Packaging Security audits shall occur at least yearly and when there are major changes to the building or equipment. Obsolete/unused printed packaging materials shall be disposed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

Facility Name: <i>Rigid Plastic Company</i>	Date: <i>September 7, 20XX</i>
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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
Receiving						
<i>Raw material receiving (resin, colorant, inks, corrugate)</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>
Warehouse						
<i>Storage of raw materials in the warehouse</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>
Injection Molding						
<i>Inject plastic into mold form part</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>
Automation						
<i>Automation equipment removes part from mold</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>
Packaging						
<i>Parts are packed into a box and labeled, then places onto a skid</i>	<i>None</i>	<i>None</i>	<i>YES - Mixed resins and product in a box due to poor changeover. Mixed Skids of finished product</i>	<i>CCP 3 - Line Changeover process ensures all components and resin are correct for next job. CCP 4: Pallet scanner to ensure only one finished product per</i>	<i>Possible metal contamination</i>	<i>CCP 1 : Metal Detection</i>

				<i>skid.</i>		
Warehouse	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>
<i>Storage of finished product in warehouse</i>						
Printing						
<i>Printing artwork on to containers and lids</i>	<i>None</i>	<i>None</i>		<i>CCP 3 - Line Changeover process ensures all components and labels are correct for next job.</i>		
Packaging						
<i>Packaging of printed containers in corrugated boxes and applying labels then placement onto skids</i>	<i>None</i>	<i>None</i>	<i>Yes - Mixed Skids of finished product</i>	<i>CCP 4: Pallet scanner to ensure only one finished product per skid.</i>	<i>Yes - Possible metal contamination</i>	<i>CCP 1 : Metal Detection</i>
Warehouse						
<i>Storage of finished product in warehouse</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>
Shipping						
<i>Finished Product Shipping</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>
Rework						
<i>Operation to repackage product in boxes</i>	<i>None</i>	<i>None</i>	<i>Yes - Mixed types of product in rework area</i>	<i>CCP 2: Procedure allowing only one lot of product to be reworked at one time</i>	<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.

Facility Name: <i>Rigid Plastic Company</i>	Date: <i>September 21, 20XX</i>
HACCP Plan Name / Number: <i>Rigid Plastic / RDGPLA1</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.
BIOLOGICAL			
<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.
CHEMICAL			
<i>Heavy Metals (inks and coatings)</i>			<i>PP: Heavy Metals Warranty received from supplier and kept on file</i>
<i>Allergen (Mixed Skids of finished product: Possible Allergen issue)</i>	<i>Products are scanned to verify the correct boxes are on a skid</i>	<i>CCP 4: Mixed Skids</i>	
<i>Allergen (Mislabelled product in a box and mislabeled: possible allergen)</i>	<i>Procedure to ensure all products are removed and proper labels are used</i>	<i>CCP 3: Line Changeover /Label Control</i>	
<i>Allergen—(mixed product in a box: potential allergen issue)</i>	<i>Procedure defining only one finished product allowed to be reworked at one time</i>	<i>CCP 2: Rework</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.
PHYSICAL			
<i>Wood Splinters, Nails, Other Extraneous Materials from Wooden Pallets</i>	<i>Metal Contamination</i>	<i>CCP:1 Metal Detection</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.