Chapter 17 PUTTING IT ALL TOGETHER— How to Develop a FSMA Food Safety Plan

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PREVENTIVE CONTROLS ARE BASED ON HACCP. THE FOLLOWING IS A STANDARD HACCP PLAN FORM.

HACCP PLAN FORM

Firm Name

Firm Address,

Firm Contact, Phone #, Email

Product Description

Method of Storage and Distribution, including during shipment

Intended Use and Consumer

CRITICAL CONTROL POINT	SIGNIFICANT HAZARDS	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTIONS	VERIFICATION	RECORDS
			WHAT	HOW	FREQUENCY	WHO			

Signature of Company Official **Date**

Printed Name of Company Official

Adapted from A.A.Saulo, HACCP course, 2015.

JUST AS IN HACCP, WE PERFORMED THE PRELIMINARY STEPS (NOT REQUIRED by FSMA LAW IN PREVENTIVE CONTROLS BUT ARE USEFUL)

Preliminary Step —
Assembling the Food Safety Team

Firm Name: **Contact Name:** **Page**

Firm Address: **Contact Telephone/fax:**

Plant #: **Contact Email:**

Food Safety Team Members

Name	Department	Title	Training

Food Safety Team Alternates

Name	Department	Title	Training

Management Signature	Date

Adapted from A.A.Saulo, HACCP course, 2015.

Preliminary Steps

Activity
1. Assemble the food safety team
2. Describe the product and its distribution
3. Describe the intended use and consumers of the food
4. Develop a flow diagram and describe the process
5. Verify the flow diagram

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USING THE PRODUCT FLOW DIAGRAM, WE PERFORMED THE FIRST REQUIRED STEP, THE WRITTEN HAZARD ANALYSIS, AND DETERMINED THE HAZARDS FOR *EACH* PROCESS STEP.

Hazard Analysis

E.G. Food Company Example

Hazard Analysis	PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit		PAGE X of Y
PLANT NAME	E.G. Food Company	ISSUE DATE	mm/dd/yy
ADDRESS	360 Culinary Circle, Mytown, USA	SUPERSEDES	mm/dd/yy

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
From flow diagram	B C P	Identify potential hazards that **may be** introduced or increase at this step	Decide if the hazards are significant		Provide a reason for "yes" or "no" in column 3 when a potential hazard is identified. Optional to justify a "None" in column 2.	For each **significant** hazard ("Yes" in column 2), identify preventive controls (**process, food allergen, sanitation, supplier or other**) that are applied at this step or later	Indicate if the preventive control is applied at this step or later in the process	

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WHEN A HAZARD IS IDENTIFIED THAT IS EXISTING OR REASONABLY FORESEEABLE, A PREVENTIVE CONTROL IS REQUIRED.

Hazard Evaluation (Hazard Analysis)

E.G. Food Company Example

Hazard Analysis	PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit		PAGE X of Y
PLANT NAME	E.G. Food Company	ISSUE DATE	mm/dd/yy
ADDRESS	360 Culinary Circle, Mytown, USA	SUPERSEDES	mm/dd/yy

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control? Yes		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	No
Receiving refrigerated ingredients – liquid pasteurized egg	B	Vegetative pathogens such as *Salmonella*	X		While pasteurization minimizes the likelihood of *Salmonella* USDA recommends the product be used in cooked foods. Experience has shown *Salmonella* occasionally occurs in this ingredient.			
	C	Allergen – egg	X		Egg is an allergen that must be labeled to inform consumers. Allergen cross-contact is not an issue – all products contain egg.			
	P	None						

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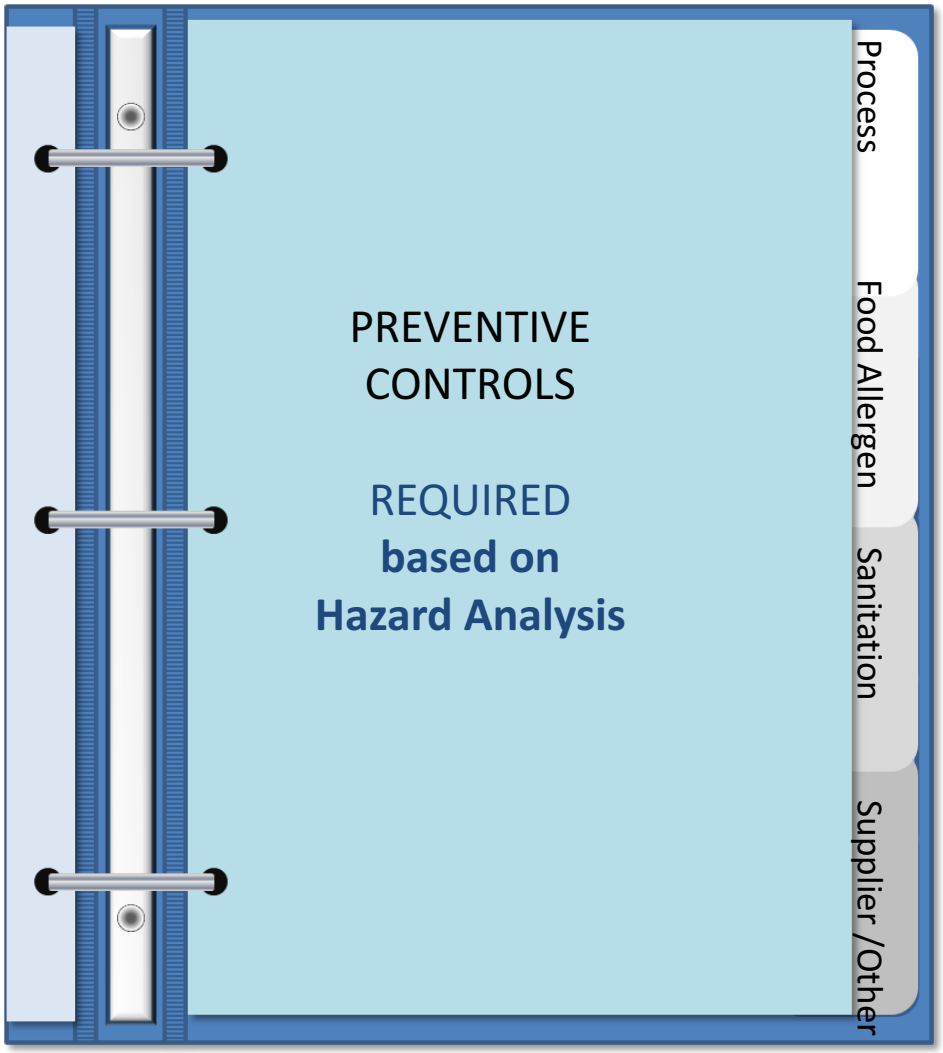
There are Several Preventive Controls



Process preventive controls
- Process specific controls discussed in Chapter 9

Food allergen preventive controls
- Accurate labeling
- Cross-contact prevention
- See Chapter 10

Sanitation preventive controls
- Environmental pathogens
- Cross-contamination, cross-contact
- See Chapter 11

Other preventive controls
- If needed

Supply-chain preventive controls
- See Chapter 12

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HERE ARE SOME EXAMPLES OF PREVENTIVE CONTROLS REQUIRED TO CONTROL A HAZARD IDENTIFIED IN A HAZARD ANALYSIS.

Hazard Evaluation (Hazard Analysis)

E.G. Food Company Example

Hazard Analysis	PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit		PAGE X of Y
PLANT NAME	E.G. Food Company	ISSUE DATE	mm/dd/yy
ADDRESS	360 Culinary Circle, Mytown, USA	SUPERSEDES	mm/dd/yy

(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Receiving refrigerated ingredients – liquid pasteurized egg	B	Vegetative pathogens such as *Salmonella*	X		While pasteurization minimizes the likelihood of *Salmonella* USDA recommends the product be used in cooked foods. Experience has shown *Salmonella* occasionally occurs in this ingredient.	**Process Control** - subsequent cook step		X
	C	Allergen – egg	X		Egg is an allergen that must be labeled to inform consumers. Cross-contact is not an issue – all products contain egg.	**Allergen Control** – allergen labeling at subsequent step		X
	P	None						

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Hazard Analysis

E.G. Food Company Example

PRODUCT: Omelet – Plain, Cheese, and Cheese Biscuit							PAGE X of Y
PLANT NAME	E.G. Food Company				ISSUE DATE		09/21/2015
ADDRESS	360 Culinary Circle, Mytown, USA				SUPERSEDES		08/06/2015
(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Receiving frozen ingredients – biscuits *	C	Allergen – wheat	X		Wheat is an allergen that must be labeled to inform consumers. Allergen cross-contact with other products must be controlled because some products do not contain wheat.	**Allergen Control** – **allergen labeling** at other steps **Sanitation Control** – at a subsequent step to **prevent allergen cross-contact**		X

*One of several Allergen Controls identified in the Hazard Analysis

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E.G. Food Company Example

Hazard Analysis		PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit			PAGE X of Y
PLANT NAME	E.G. Food Company			ISSUE DATE	mm/dd/yy
ADDRESS	360 Culinary Circle, Mytown, USA			SUPERSEDES	mm/dd/yy

(1) Ingredient/ Processing Step	(2)	Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Assemble, wrap	B	Introduction of environmental pathogens such as *L. monocytogenes*	X		Recontamination may occur if sanitation control is not in place.	**Sanitation Controls** – prevent recontamination	X	
	C	Allergen cross-contact from other products handled at this step; e.g., Cheese Omelet Biscuit	X		Biscuits could introduce wheat allergen to other products without control	**Sanitation and Allergen Controls** – prevent cross-contact	X	

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E.G. Food Company Example

Hazard Analysis	PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit		PAGE 10 of 36
PLANT NAME	E.G. Food Company	ISSUE DATE	mm/dd/yyyy
ADDRESS	360 Culinary Circle, Mytown, USA	SUPERSEDES	mm/dd/yyyy

(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Receiving refrigerated ingredients – pasteurized process cheese	B	Vegetative and sporeforming pathogens such as *Salmonella,* pathogenic *E. coli, L. monocytogenes* and *C. botulinum*	X		Pathogens listed were identified as significant by ICMSF (2005) in process cheese. These hazards must be controlled when the cheese is made.	**Supply-chain** Control – approved supplier and 3rd party supplier audit by a qualified auditor	X	

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IN HACCP, WE IDENTIFIED CCPs ONLY AND AIMED TO CONTROL ONLY THOSE CCPs.

HACCP PLAN FORM

Page___

Firm Name

Firm Address,

Firm Contact, Phone #, Email

Product Description

Method of Storage and Distribution, including during shipment

Intended Use and Consumer

CRITICAL CONTROL POINT	SIGNIFICANT HAZARDS	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTIONS	VERIFICATION	RECORDS
			WHAT	HOW	FREQUENCY	WHO			

Signature of Company Official **Date**

Printed Name of Company Official

Adapted from A.A.Saulo, HACCP course, 2015.

UNDER FSMA, WE AIM TO MANAGE EACH PREVENTIVE CONTROL.

Process Preventive Control

E.G. Food Company Example

PRODUCT: Omelet – Plain, Cheese, Cheese Biscuit — PAGE 1 of X

PLANT NAME: E.G. Food Company — ISSUE DATE mm/dd/yy

ADDRESS: 360 Culinary Circle, Mytown, USA — SUPERSEDES mm/dd/yy

Process Control	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Cook	Vegetative pathogens such as *Salmonella*	Omelet surface temper-ature is ≥158°F (70°C) instan-taneous before transfer to assembly table	Omelet surface temper-ature is ≥158°F (70°C)	Infrared surface thermo-meter	Each cook station, 4 times per shift, about every 2-3 hours	QA tech-nician or designee	Hold product back to the last good check and evaluate - rework, discard, or release. Determine root cause – retrain or correct as appropriate .	Review of Cook Log, Corrective Action and Verification records within 7 working days Daily accuracy check for thermo-meter Annual calibration of thermo-meter	Cook Log – cook temp by QA technician Corrective Action records Verification records, including Validation study

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EACH PREVENTIVE CONTROL IS MANAGED WITH A HACCP-BASED IMPLEMENTATION PROGRAM (PRODUCING IMPLEMENTATION RECORDS).

Implementation records include:

- *monitoring,*
- *corrective actions*
- *verification*
- *validation,*
- *supply-chain*
- *training)*

Allergen Preventive Control– Label review upon receipt (Step 1)

E.G. Food Company Example

PRODUCT: Omelet - Plain — PAGE 1 of X

PLANT NAME: E.G. Food Company — ISSUE DATE mm/dd/yy

ADDRESS: 360 Culinary Circle, Mytown, USA — SUPERSEDES mm/dd/yy

Allergen Control	Hazard(s)	**Criterion**	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Receiving packaging (labeled carton)	Undeclared allergens – egg, milk, soy (wheat in biscuit only)	All finished product labels must declare the allergens present in the formula per listing	Ingredient listing and allergen informa-tion matches product	Visual check of carton label to match product formula	Before release to production	Label coordi-nator	If label is incorrect, reject labels and return to supplier or destroy. Identify root cause and conduct training as needed to prevent recurrence	Review of Label verification, Corrective Action and Verification records **within 7 working days**	Allergen Label Verifica-tion listing; Allergen Label Verifica-tion log; Corrective Action records;

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Allergen Preventive Control– Label review at application on product (Step 2)

E.G. Food Company Example

PRODUCT: Omelet - Plain — PAGE 1 of X

PLANT NAME: E.G. Food Company — ISSUE DATE mm/dd/yy

ADDRESS: 360 Culinary Circle, Mytown, USA — SUPERSEDES mm/dd/yy

Allergen Control	Hazard(s)	Para-meter	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Fill, weigh, label	Undeclared allergens – egg, milk, soy (wheat in biscuit only)	All finished product must have correct labeled carton	Label number matches product	Visual check of carton number to match product	Beginning and end of run and when label stock is changed	Fill line opera-tor	If label is incorrect, segregate product, inspect back to the last good check, relabel product; Identify root cause and conduct training as needed to prevent recurrence	Review of Label Check, Corrective Action and Verification records **within 7 working days**	Allergen Label Verification listing Allergen Label Check Log; Corrective Action records; Verification records

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THERE IS NO STANDARD FORMAT FOR A HACCP-BASED FORM. THE PREVIOUS ONES WERE TABULAR. SOME OF THE NEXT ONES ARE NOT (BUT MAY BE EASILY CONVERTED TO A TABULAR FORM).

Assemble, Wrap Table Sanitation

Purpose: Cleaning and sanitizing of the assembly and wrapping table is important to remove potential allergens and reduce microbial cross-contamination or recontamination with environmental pathogens that may impact product safety.

Frequency:

Cleaning: At lunch break, after Cheese Omelet Biscuit production, at the end of daily production.

Sanitizing: Before operations begin, at lunch break, after Cheese Omelet Biscuit production, and at the end of daily production.

Who: Sanitation team member

Procedure:

Note: Blue cleaning tools are to be used ONLY for cleaning after a cheese biscuit run to reduce the potential for unintentional allergen transfer.

Cleaning

1. Remove unused packaging material to an area at the end of the shift to prevent it from getting wet. Cover it during the lunch clean up.
2. Remove gross soil with a squeegee.
3. Wipe table surface with a clean cloth dipped in ABC cleaning solution (Y oz. per gallon).
4. Rinse table with clean water. Detergent remaining on the surface can inactivate the sanitizer.

Sanitizing

1. Spray table surface with 200 ppm quaternary ammonium compounds solution, ensuring that entire surface is covered.
2. Allow table to air dry, about 5 minutes. Contact time required per label – 1 minute.

Monitoring (at frequency indicated above)**:**

Inspect table for residual soil and cleanliness. Record on Daily Sanitation sheet.

Use test strip to measure the quat concentration BEFORE application. Record on Daily Sanitation sheet

Corrections:

If residual soil is observed on the table, reclean and sanitize.

If quat is not at the proper concentration, make a new solution.

Records: Daily Sanitation Sheet

Verification: Supervisor reviews and signs Daily Sanitation Sheet within 7 working days

Easy to read text is in Appendix 3

PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit
PLANT NAME: E.G. Food Company ISSUE DATE mm/dd/yyyy
ADDRESS: 360 Culinary Circle, Mytown, USA SUPERSEDES mm/dd/yyyy

Daily Sanitation Control Record – Omelet Line

DATE:

Sanitation Area and Goal	Pre-Op Time:	Start Time:	Lunch Break Time:	Post-Op Time:	Comments and Corrections	Operator Initials
Condition & Cleanliness of Food Contact Surfaces						
• Equipment cleaned and sanitized (S/U)*						
• Sanitizer type and strength: *Quaternary ammonium compound, 200 ppm*						
Omelet line (ppm)+						
Dish room dip tank (ppm)+						
Prevention of Cross-Contact						
• Cleaning after Cheese Omelet Biscuit (S/U/NA)&						
Condition & Cleanliness of Non-food Contact Surfaces						
• Floors and wall splash zones cleaned and sanitized (S/U)						
• Sanitizer type and strength: *Quaternary ammonium compound, 400-600 ppm*						
Floors and wall splash zones (ppm)+						

* S = Satisfactory, U = Unsatisfactory

+ Enter ppm measured per test strip

& NA = not applicable because Cheese Omelet Biscuit run after other products

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Verification signature:	Date:

Supply Chain Preventive Controls

- Approved Suppliers for ingredients requiring a supply-chain-applied control

Ingredient requiring control	Approved supplier	Hazard requiring control	Date of approval	Verification method	Verification records

- Ingredients with history of hazards

Ingredient Supplier	Hazard	Parameter	What	How	Frequency	Who	Corrective Action	Verification	Records

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THUS, A HACCP PLAN FORM IS VERY SIMILAR TO A PREVENTIVE CONTROL FORM.

HACCP Plan Form

CCP	Significant Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			

Preventive Control Form

Process Control	Hazard(s)	Critical Limits/ Parameters or Values	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			

Exercise Workbook, Chapter 9, pp. 12-13, landscape format.

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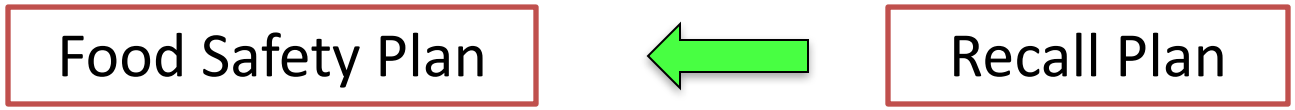
WHEN A HAZARD IS IDENTIFIED REQUIRING A PREVENTIVE CONTROL, A RECALL PLAN IS THEN MANDATED.

Recall Plan

- When a hazard is identified during hazard analysis and it requires a preventive control, a recall plan is mandated.



IN SUMMARY, THE FOOD SAFETY PLAN =

HAZARD ANALYSIS +

PREVENTIVE CONTROLS (EACH WITH AN IMPLEMENTATION PROGRAM) +

RECALL PLAN

Make Your Own Food Safety Plan

- Describe your facility. Draw a plant schematic diagram.
- Design your GMP & Prerequisite Programs (see Checklist of Programs for Food Safety)
- Define Preliminary Steps
- Conduct a written Hazard Analysis
- Determine your Preventive Controls
  - Process (CCPs)
  - Food Allergen
  - Sanitation
  - Supply-Chain

Make Your Own Food Safety Plan (cont'd)

- Design your Recall Plan
  - Important contacts
- Analyze the Food Safety System
- Keep records and meet recordkeeping requirements
  - Form requirements
  - Management review and signature

FDA's Food Safety Plan Builder V1.0

https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm539791.htm

Using this tool is optional and does not mean that the resulting food safety plan and other programs are approved by the FDA and comply with the FDA requirements.

Some Thoughts…

- CCPs in HACCP are usually transposed as Process Preventive Controls
- Or, there may be preventive controls not in the HACCP plan (e.g., environmental monitoring, sanitation procedures, verification procedures)
- Recordkeeping and validation of preventive controls will likely contribute the greatest burden to smaller firms

THE END

Instructions

- Please put away all your course materials. Leave only a pen.
- Complete the Course/Instructor Evaluation Form.
- Return the completed evaluation form to the Assistant.
- Take the examination (this is not an open-book exam).

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