



Moving from HACCP to “HARPC”

Practical Steps to Compliance

March 19, 2016



TABLE 29—A COMPARING THE FOOD SAFETY PLAN TO HACCP PLANS

Requirements	PC Rule	NACMCF HACCP Guidelines	Codex HACCP Annex	Federal HACCP rules for juice, seafood, and meat and poultry
Written plan .. Who is responsible for preparing the plan?	<p>Yes</p> <p>The owner, operator or agent in charge of a facility must prepare, or have prepared, and implement a written food safety plan. The food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals.</p>	<p>Yes</p> <p>A HACCP team may need assistance from outside experts knowledgeable in the hazards associated with the product and process.</p>	<p>Yes</p> <p>Individual businesses, with advice when necessary from other sources.</p>	<p>Yes.</p> <p>The processor.</p>
What does the plan contain?	<ul style="list-style-type: none"> • Written hazard analysis • Written preventive controls • Written supply-chain program. • Written recall plan • Written procedures for monitoring the implementation of the preventive controls. • Written corrective action procedures. • Written verification procedures. 	<ul style="list-style-type: none"> • Written hazard analysis • Must include the hazard, the CCPs, and critical limits. • Must include monitoring procedures. • Must include corrective actions. • Must include verification procedures. • Must include recordkeeping procedures. 	<ul style="list-style-type: none"> • Written hazard analysis • Must include CCPs and critical limits. • Must include monitoring procedures. • Must include corrective actions. • Must include verification procedures. • Must include records 	<ul style="list-style-type: none"> • Written hazard analysis. • Must list all food safety hazards that are reasonably likely to occur, CCPs, and critical limits. • Must list monitoring procedures. • Must include corrective action procedures. • Must include verification procedures; • Must include recordkeeping procedures.
Is oversight required by a person qualified by training and experience?	<p>Yes</p>	<p>Yes</p>	<p>Yes</p>	<p>Yes.</p>





Overview

- What's FDA Up To?
- Where do you fall?
- Training Programs
- Evaluate & update GMPs
- Establish Preventive Controls
- Implement verification & validation
- Supply Chain updates
- Managing the process to compliance



What's FDA Up To?

- Fact-finding!
 - Data gathering
 - Market sampling
 - Facility visits

- Inspector training



Some Things We're Hearing

- Hand washing stations
- Recall plan
- Customer complaints program
- Environmental monitoring & product sampling



shutterstock · 77971477





Where Do You Fall?

Rules

- Preventive Controls
- Produce Safety
- Foreign Supplier Verification & ATP
- Sanitary Transportation
- Intentional Adulteration

What You Do

- Primary Production Farm
- Secondary Activities Farm
- Mixed-Type Facility
- Processor
- PC with exemption
- Importer



Qualified Individuals

- PCQI: A PC Rule requirement

“A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.”
Section 117.3
- Qualified auditors
- Qualified individuals





Training Programs

- Identify & document training needs for each position
- Matrix approach may be helpful

Last Name	First Name	Start Date	Employee #	Inspector 1										Inspector 2					Inspector 3										
				Fundamentals			Inshell	Walnut Inspection		Walnut Meats Inspection				Incoming Walnuts Inspection			Shelled Almond Inspection												
				Safe Work Practices & Safety Policies	Good Manufacturing Practices	Professional Conduct	Expenses & Time Reporting	Sampling Protocols	Inspection Technique	Grading & USDA Standards	Paperwork - Domestic	Paperwork - Export & Custom	W/2, Container Markings & Traceability	Sampling Protocols	Inspection Technique	Grading & USDA Standards	Paperwork - Domestic	Paperwork - Export & Custom	Stamping, Container Markings & Traceability	Sampling Protocols	Inspection Technique	Grading & USDA Standards	Paperwork - Domestic	Paperwork - Export & Custom	Scheduling	Training Inspectors	Customer contacts & site familiarity	Safety Policy & Accident Procedures	
Smith	John	11/2011	2																										





PCQI Tasks – 117.180

Conduct or oversee

- Plan preparation
- Plan reanalysis – 3 years
- Validation of PCs – within 90 days
- Record review – within 7 days
- Written justifications
 - If time frames above not followed
 - If validation is not required



GMP Update



- Additional Focus on allergen cross-contact!
 - Cleaning
- Review:
 - Equipment & tools usage
 - Employee practices
 - Product handling
 - Air handling
- Thorough verification of cleaning effectiveness
- Cleaning chemicals – letter of guarantee





DETERMINING PREVENTIVE CONTROLS



HACCP vs. “HARPC”: Hazard Analysis Comparison

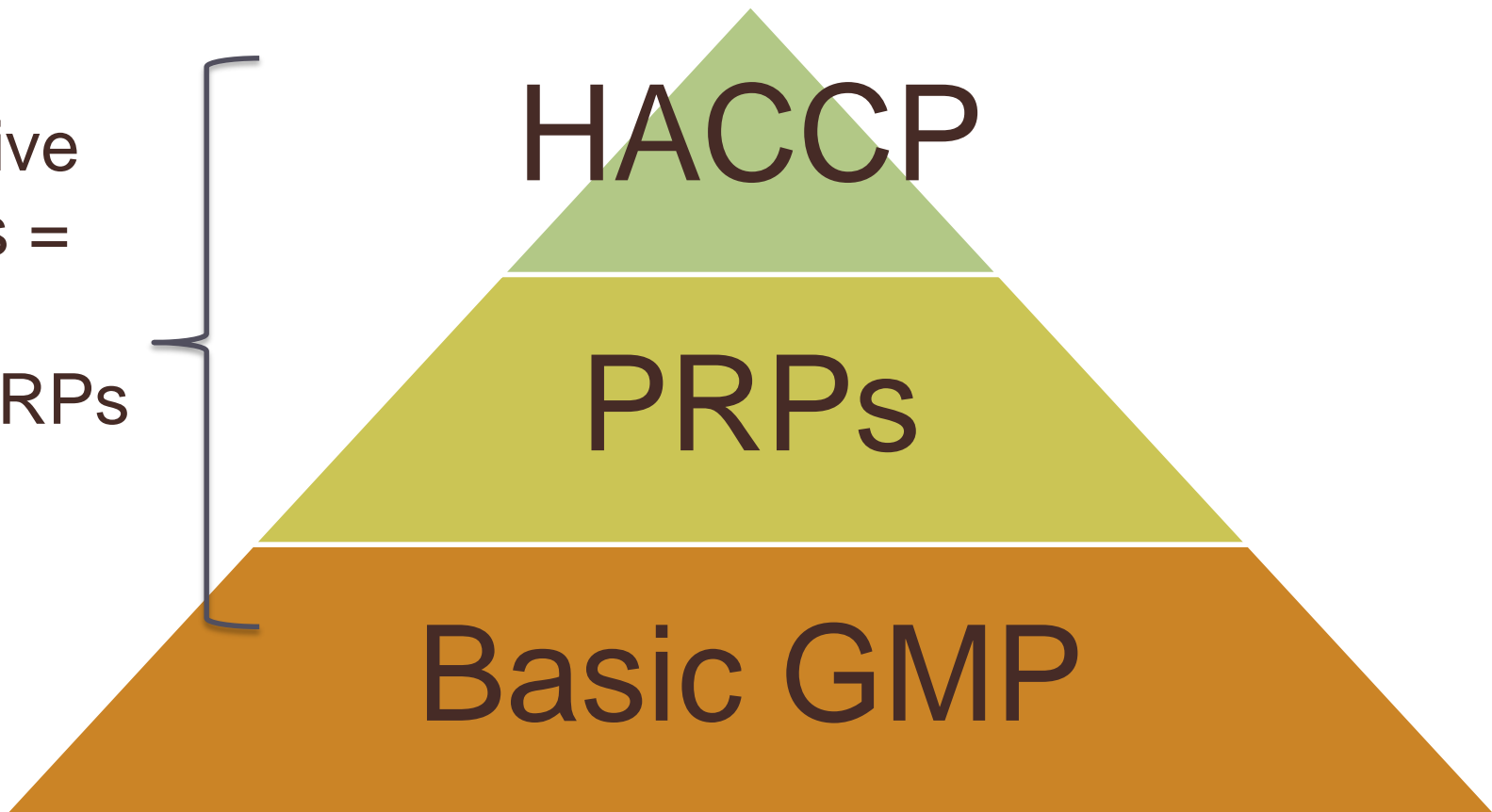


- HACCP: Focus = CCPs
 - Builds on existing prerequisite programs (PRPs)
 - Analyzes potential hazards based on existing programs
 - Establishes CCPs to control remaining significant risks, after PRPs are effectively implemented
- HARPC: Focus = All Preventive Controls
 - Analyze potential hazards to consumers
 - Identify measures to control those hazards (CCP or other)
 - Manage controls for any “significant hazards” / “hazards requiring a preventive control,” in a manner similar to a CCP

HACCP vs. Preventive Controls



Preventive
Controls =
CCPs +
Some PRPs

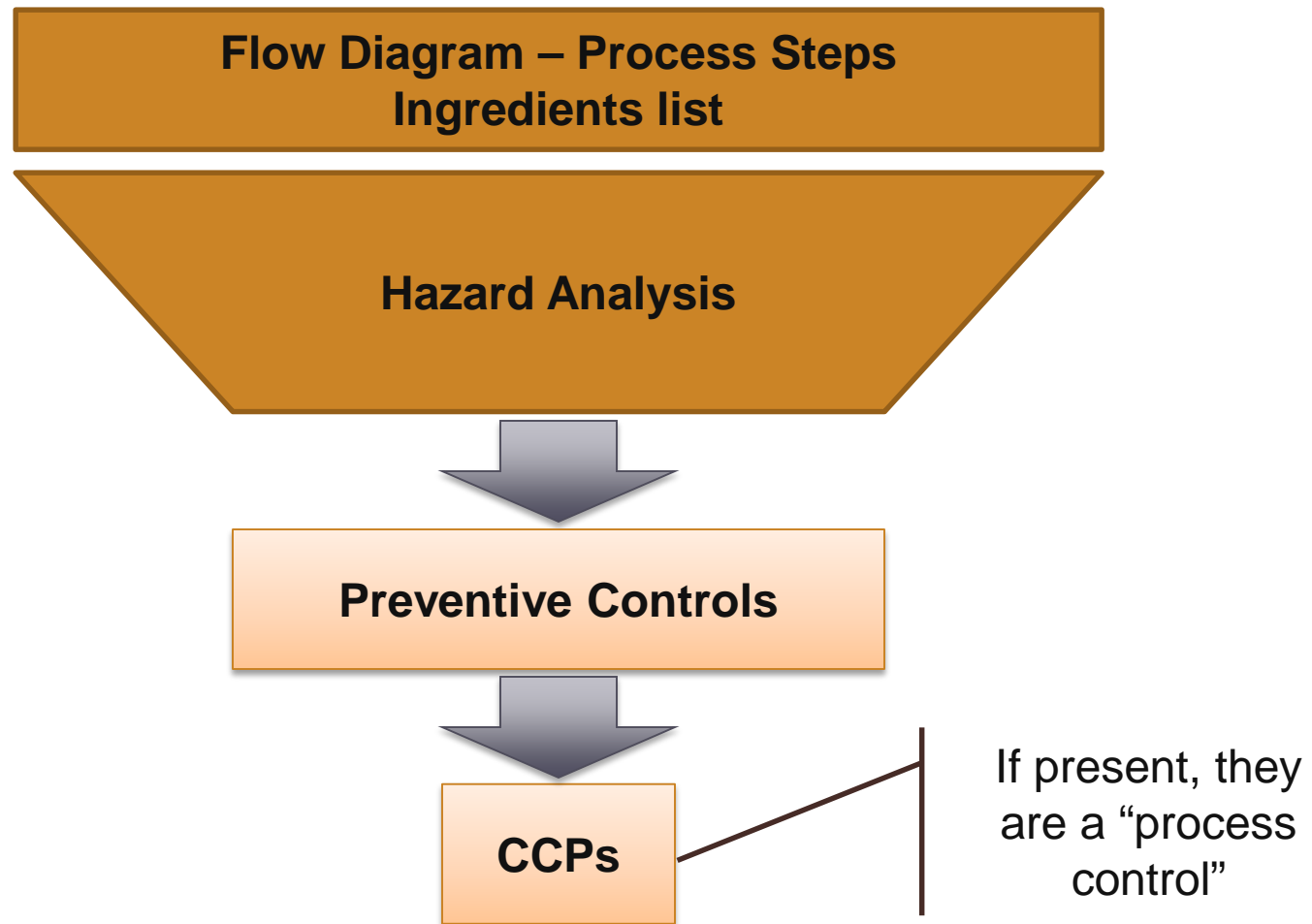




Hazard Analysis – The Driver

- “Must be written regardless of its outcome”
- Spend time digging
 - FDA web site, RASFF, CFIA
 - USP’s food chemical codex, foodfraud.org
 - Gather data to assess your current controls
- Identify hazards requiring a preventive control
 - Known or reasonably likely to occur
 - Based on severity & likelihood
- Determine controls for them
- Team approach not required but recommended
- *Should include radiological, environmental, intentional contamination hazards*

Preventive controls & HACCP





SEARCH

- [Home](#)
- [Food](#)
- [Drugs](#)
- [Medical Devices](#)
- [Radiation-Emitting Products](#)
- [Vaccines, Blood & Biologics](#)
- [Animal & Veterinary](#)
- [Cosmetics](#)
- [Tobacco Products](#)

Safety

- [Home](#)
- [Safety](#)
- [Recalls, Market Withdrawals, & Safety Alerts](#)
- [Archive for Recalls, Market Withdrawals & Safety Alerts](#)



Archive for Recalls, Market Withdrawals & Safety Alerts

Search the Firm Recalls Section

SEARCH

Related Links

- [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#)

Recalls, Market Withdrawals, & Safety Alerts
Archive for Recalls, Market Withdrawals & Safety Alerts
2016
2015
2014
2013
2012
2011
2010
2009
2008
2007
2006
2005
2004

Recalls & Alerts

- [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#)
- [FDA 101: Product Recalls](#)
- [Major Product Recalls](#)





Canadian Food Inspection Agency



- About the CFIA ▾
- Food ▾
- Animals ▾
- Plants ▾
- Guidance Document Repository ▾

[Home](#) → [About the CFIA](#) → [Newsroom](#) → [Food Recall Warnings](#) → Complete Listing

Acts and Regulations

Newsroom

Food Safety System

News Releases

Prosecution Bulletins

Statement

Stay Connected

Food Recall Warnings

Complete listing of all recalls and allergy

Select from the filters below to specify which recalls you want to review. Additional information reasons filter are found in the [recall glossary](#).

Year:

Past 4 months ▾

Reason:

All ▾

Class:

All ▾

Distribution:

All ▾

Public Warning:

Yes ▾

Go

Reset the filters



Notifications list New search

Search Page

Get results Clear form

Notification

Reference

Subject or and

Notified by

Open alerts

Type

Type

Classification withdrawn

Basis

Date

Week current week [16]
 previous week [15]
 of

Notified between and (dd/mm/yyyy)

Product

Category

Flagged as

Country



Home

Search

Report Fraud

Search

Enter a search item below.

GO

	Unique ID	Regulatory Status	Report Type	Ingredient Category	Ingredient	Adulterant	Type of Fraud	Pub Year
+	36550	Food Ingredients	Media	Dairy products and milk derivatives	Yogurt candy	Melamine	Replacement	2014
+	34198	Food Ingredients	Scholarly	Dairy products and milk derivatives	Yogurt (ovine)	Milk (bovine)	Replacement	2002

The format



(1) Ingredient/ Processing Step	(2) <u>Reasonably foreseeable</u> food safety hazards introduced, controlled or enhanced at this step (B=biological; C=chemical, including radiological; P=physical)	(3) Hazard severity	(4) Is hazard a significant hazard?	(5) Justify your decision for column 4	(6) What <u>preventive</u> control(s) are applied to significantly minimize or prevent the food safety hazard?	(7) Is this step a CCP?
--	---	---------------------------	--	---	--	----------------------------------

(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?		(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? <i>Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control</i>	(6) Is the preventive control applied at this step?		
		Yes	No			Yes	No	
	B							
	C							
	P							

A Combined Approach



(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential hazards require a Preventive Control? (FSMA)	(4) Risk Number from Hazard Analysis Matrix (HACCP)	(5) Are any hazards significant ? (HACCP)	(6) Justify your decision for columns 3/4	(7) What preventive control measures can be applied to significantly minimize or prevent the hazards?	(8) Is the Preventive Control applied at this step?	(9) Is this step a CCP? If so, what CCP #? (HACCP)
Ingredient	B							
	C							
	P							
Process Step	B							
	C							
	P							





Required Verification

As appropriate to the facility, the food, and the nature of the control:

- Validation of preventive controls – **process** PCs
- Verification of monitoring and corrective actions
- Calibration of process monitoring and verification instruments
- Product testing, environmental monitoring (exposed RTE Foods)
- Records review



Supply Chain Program



- Must have a risk-based program which ensures hazards are controlled
- Suppliers must be approved
- Must determine, document, and conduct appropriate supplier verification activities
- Controls applied in the supply chain must be verified

- Aligns with Foreign Supplier Verification rule, Accreditation of Third Party Auditors rule, Sanitary Transportation



Downstream control

- If a “hazard requiring a PC” is controlled by your customer (or their customer):
 - Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”
 - Annually obtain from your customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard.





FSV Rule

- Use FDA decision tree to determine applicability
- Controls still driven by hazard analysis
- Determine & document applicable controls based on risk
- Again, approve suppliers before use
- Import documentation format will change
 - To import, obtain a Dunn & Bradstreet DUNS number (importer of record)



Supply Chain - Some Notable Items



- GAP or GFSI are not a FSMA equivalent.
- If a “hazard requiring a PC” is controlled by your supplier, on-site audit is required
- Items for R&D not applicable
- Importers are deemed in compliance with most of FSVP when they:
 - Comply with PC supply-chain provisions
 - Implement preventive controls under PC regulation for hazards in food they import
 - Are not required to implement a preventive control under certain PC provisions (food cannot be consumed without further control, or there is a documented control later in the supply chain)

Managing Supplier Documents



Supply Chain Documentation								
Supplier	Item Supplied	FSMA Rule	Compliance Date	Exemptions	Identified Hazards Requiring a PC	Control	Required Document	Due Date
Peanutco	Peanuts - Roasted	Preventive Controls	September-17	None	Salmonella, aflatoxin	Supplier pasteurization, CoA, lab analysis	FSMA compliance audit	3/17/2017
							Validation of roasting process	3/1/2016
Nutty Neighbors	Peanuts - Raw in shell	Produce Safety	September-19	Very Small	Salmonella, aflatoxin	Pasteurized here or by customer, CoA, lab analysis	Letter of guarantee - FSMA PS compliance	11/15/2018
							Attestation - very small supplier	11/15/2018
Maritime Bliss	Salt	Preventive Controls	September-16	None	None	N/A	Letter of guarantee	5/1/2016
Customer	Item Purchased	FSMA Rule	Compliance Date	Exemptions	Identified Hazards Requiring a PC	Control	Required Document	Due Date
Mrs. Peanut	Raw peanuts	Preventive Controls	September-18	None	Salmonella	Pasteurization of nuts	Letter of attestation - pasteurization of nuts	3/17/2019
							Today's Date	4/18/2016
							Today's Date + 60 Days	6/17/2016



Pulling it together: Create A To-Do List



- Review the requirements
- Document actions to take
- The list is a communication tool
 - Identify resource needs
 - Hours to implement
 - Hours to maintain
 - Capital improvements
- Track & manage work
- Communicate at-risk items
- Celebrate wins!



Project Management



Item	Hours to Implement	Hours/Month Maintenance	Responsible	Due
PCQI Training	24	N/A	Tom & Selina	May 2016
Hazard Analysis Update	10	N/A	Food Safety Team	July 2016
New Records Reviews	8	4-8	Tom, Selina, Jake	Sept 2016
Supply chain program	40	5	Tom, Denice	Dec 2016



FDA Guidance



Being prepared for release:

- Hazard analysis and preventive controls
- Environmental monitoring
- Food allergen controls
- Validation of process controls
- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule.

FDA & FSPCA TANs are available.



In Summary: Your To-Do List

- Determine where you fall & note compliance dates
- Establish training programs & begin to execute
 - PCQI
- Evaluate current GMP programs & update
- Update Hazard analysis, Determine & Document Control Points
 - Determine validations, monitoring, verification, corrective actions
- Document supplier controls based on hazard analysis
- Project management





A Few More Things

- Add facility address to documents
- Ensure HACCP plan is signed by site “agent in charge”
- Review & document retention of records
 - Equipment adequacy
 - Previous versions of documents
 - Pesticide labels
 - Others required by rule



Thank You!



Jon Kimble
Food Safety Services Manager
DFA of California
JonK@dfaofca.com

DFA CORPORATE

710 Striker Avenue
Sacramento, CA 95834
P. 916.561.5900
F. 916.561.5910

