

PEOPLE | PROPERTY | REPUTATION

ASSET PROTECTION



THE VOICE OF FOOD RETAIL 

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FSMA

Food Safety Modernization Act

What It Really Means For You



THE VOICE OF FOOD RETAIL 



Top 5 FSMA Reactions

1. I've been doing it this way for 40 years and I've NEVER gotten anyone sick!
2. "The government is trying to control everything!"
3. "What's it going to cost?"
4. "I'm just going to have to close my business"
5. "They can't expect us to do that"

Get positive about FSMA

It's not
the big
bad
boogie
monster!



What FSMA is:

RISK-BASED PREVENTATIVE CONTROLS for human food & animal food

STANDARDS for growing, harvesting, packing and holding produce for human consumption

SANITARY transportation of food

ACCREDITED third-party certification

Foreign supplier **VERIFICATION** programs

Focused mitigation strategies to **PROTECT** food against intentional adulteration

Standards for Produce

Good water quality

Testing

Raw manure

Stabilized compost

Sprouts

Animals

Personal hygiene & training

Equipment, tools
& building



Sanitary Transportation

Transportation & Equipment



Transportation Operations

Information Exchange

Training

Records



Accredited third-party certification

Recognized Accreditation Bodies

Foreign government or Private third-party

Assess certification bodies including samples of work

Monitor performance

Correct internal issues

Submit self-assessment reports

Maintain & provide records upon request

Requirements of Third-Party Certification Bodies

Must perform unannounced audits

Must notify FDA of critical violations

Competent & Objective

Verify effectiveness of corrective actions

Correct internal issues

Maintain & provide records upon request



Foreign Suppliers

Conduct a Hazard Analysis

Evaluate Risk & Supplier Performance

Supplier Verification

Corrective Actions

Exemptions and Modified Standards



Intentional Adulteration

Food Defense Plan

Actionable process

Focused mitigation strategies

Monitoring

Corrective actions

Verification

Recordkeeping

Training

Main Focus:

Bulk liquid receiving and loading

Liquid storage and handling

Secondary ingredient handling (the step where ingredients other than the primary ingredient of the food are handled before being combined with the primary ingredient)

Mixing and similar activities.

Preventative Controls



Hazard Analysis

Preventative Controls

Monitoring

Corrective Actions

Verification

Recordkeeping

Reanalyze

Executive Commitment

It's going to take time

It's going to take money

It's going to require change

It's going to require communication



Real life example of FSMA without executive commitment:



First Steps

Establish the Qualified Individual

Establish the HARPC/HACCP team



Build a Risk Matrix

Risk Profile Matrix for Hazard Analysis					
Likelihood→		Common	Known to Occur	Could Occur	Do Not Expect to Occur
Severity↓		A	B	C	D
A	Fatality	1	2	4	7
B	Serious Illness	3	5	8	12
C	Product Recall	6	9	13	17
	Customer				
D	Complaint	10	14	18	21
E	Insignificant	15	19	22	24
					25

Note: Highlighted areas indicate the need to control a quality threat through the use of a "Control Point (CP)" or a "Critical Control Point (CCP)".

Hazard(s) addressed by a CP in SOP's.

Hazard(s) addressed by a CP or CCP.

Hazard(s) addressed by a CCP.

1. Risk Assessment/Hazard Analysis

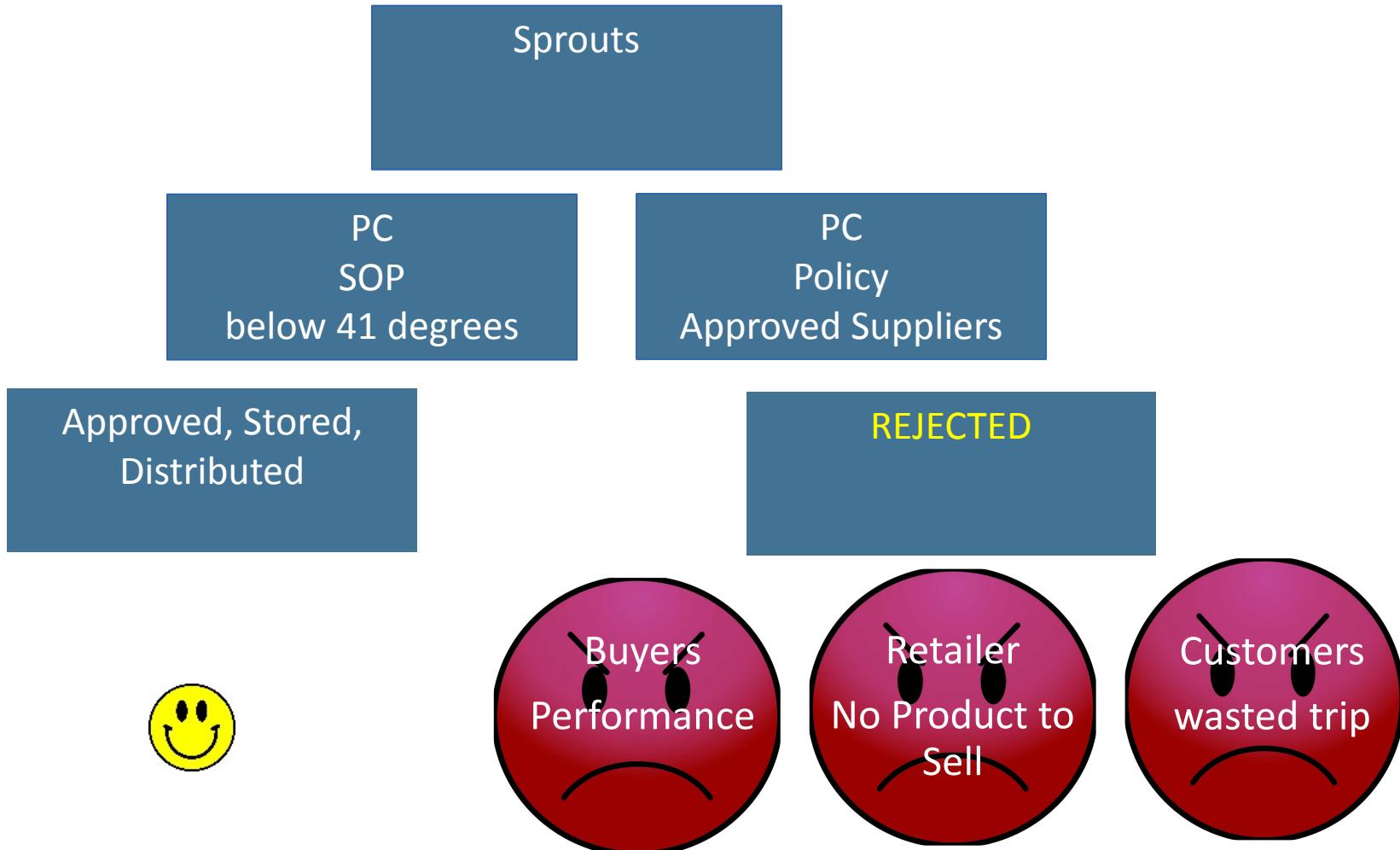
HARPC Product List

Product Name:	Produce Non-Raw Agricultural Commodity asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots & tops) and sugar beets; sour cherries, chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds & weed); eggplants; figs; horseradish; lentils; okra; peppermint; potatoes; pumpkins; winter squash; sweet potatoes						
	Insignificant Hazard						
Processing Step/Ingredient	Hazard Description Biological, Chemical or Physical		Likelihood Score	Severity Score	Significance Score	Prerequisite or Operational Program Identify & Brief Description	CCP
Produce Non-Raw Agricultural Commodity	B	NRLO	D	E	24	Purchase from Approved Suppliers.	N
	C	NRLO	D	D	25	Receiving, Storage, Shipping SOP's	N
	P	NRLO	E	D	24	cGMP's	N
Labeling Requirements:		Grade, Country of Origin					
Storage and Distribution:		Dry Storage. No temperature control during distribution.					
Shelf Life:		Varies based on quality					
Intended Market:		Retail including industrial					
Intended Use:		Cooked prior to use					
Intended Consumers:		Retail consumers of all ages including highly susceptible					
NRLO		Not Reasonably Likely to Occur					

2. Risk-Based Preventative Controls

Preventative Control	What it looks like
Approved Suppliers	GFSI or GAP audits
Standard Operating Procedure	Allergen Control
Sanitation SOP's	Cleaning a drain
cGMP's	No Jewelry
Training Programs	Monthly Read & Sign
Policies/Procedures	Illness Reporting Policy
Pest Control	Licensed Pest Control Operator

Real life Impact of PC's



3. Effective Monitoring



Recordkeeping/Logs

Values

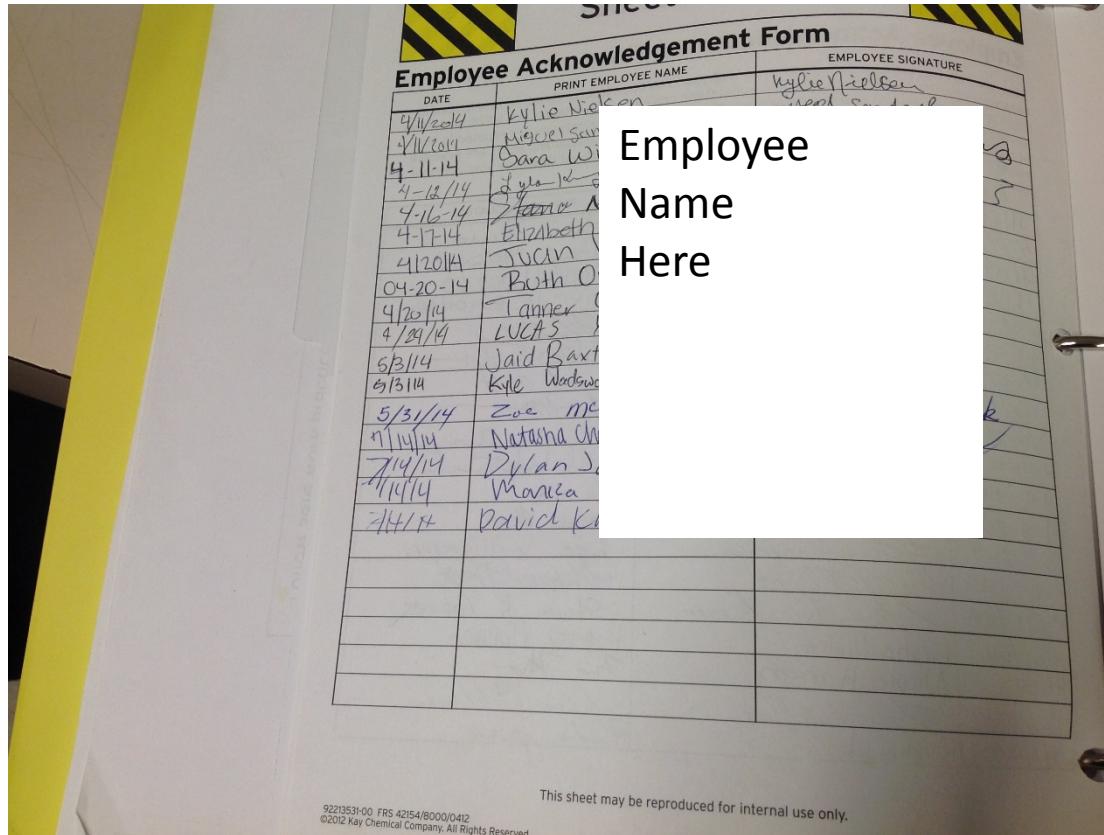
Frequency

Sign Off

Dates



Real life Impact of Monitoring

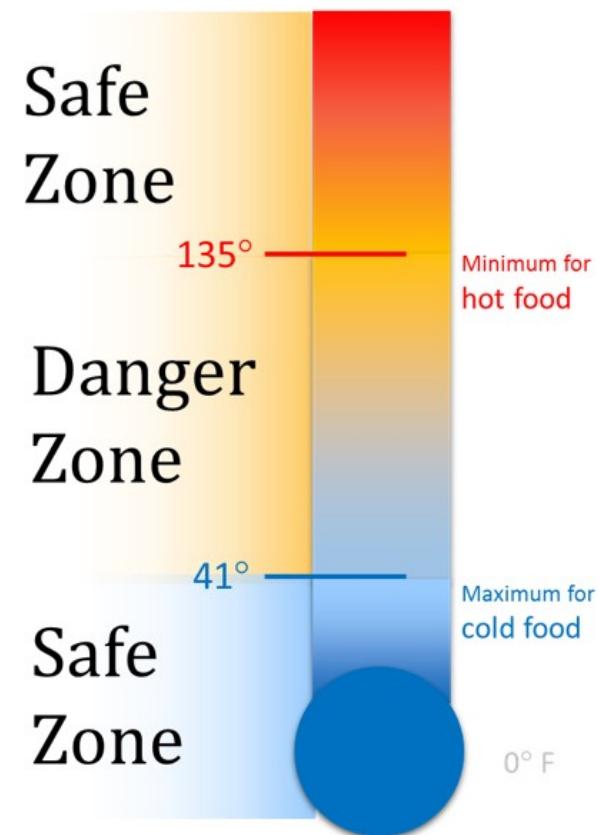


**Photo taken 03/01/2016*

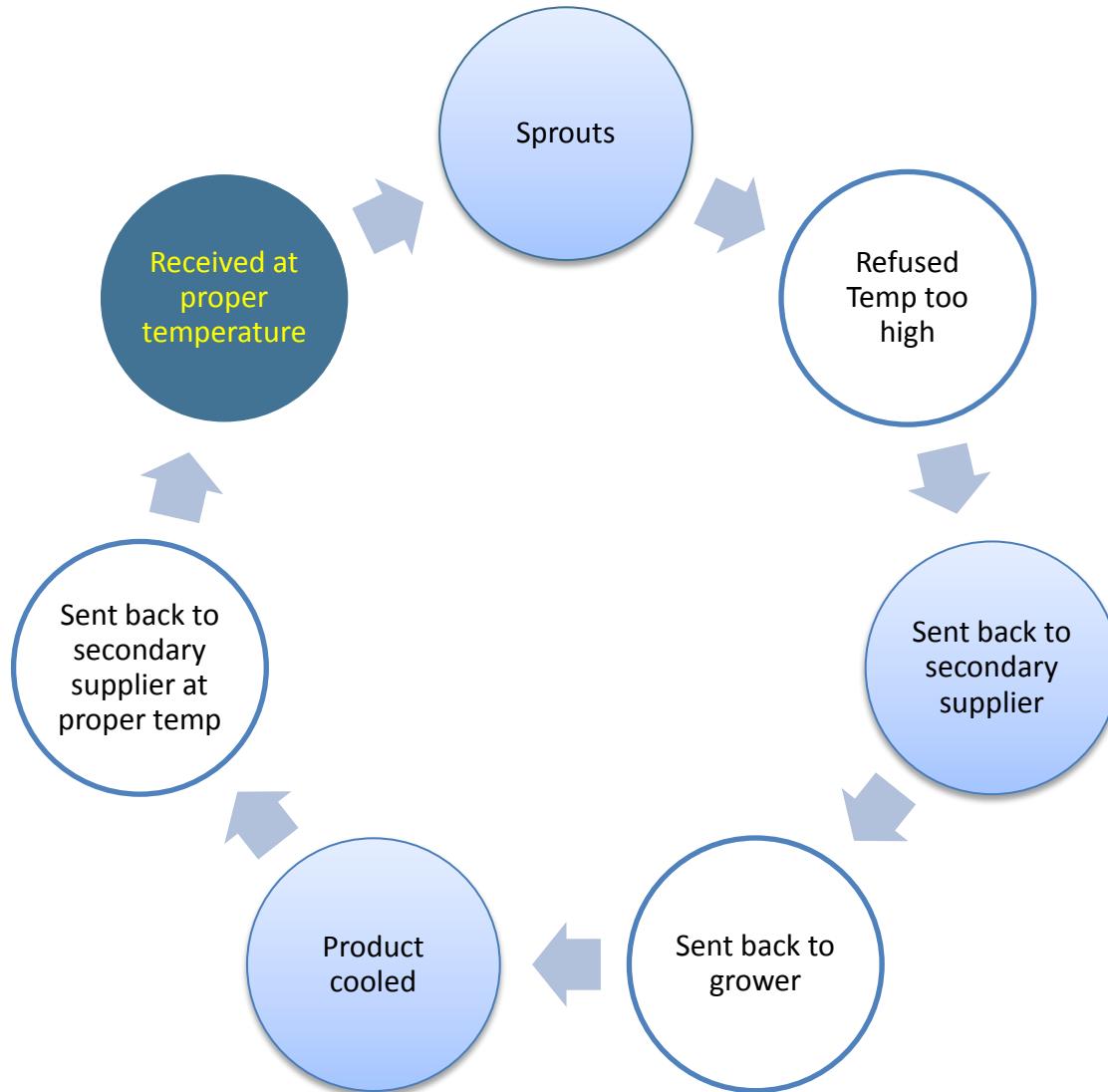
4. Corrective Actions & Corrections

Must have a predetermined corrective action plan:

1. No hazard - Release
2. Hazard
 1. Physical
 2. Biological
 3. Chemical
 4. Time/Temperature



Real life impact of corrective actions



5. Verification

Is it effective?

Is it consistent?



Calibrations

Thermometers

Microbial Testing

Environmental
Testing

Record Review

6. Recordkeeping

2 years



Approved suppliers

Trace back – Trace forward

CL's at CCP's

CP's

Monitoring Logs

Invoices/BOL

Real life impact document control approved suppliers

One supplier ABCD company:

Grow apples, cherries, pears

Company A requires a GFSI Audit sent to AAA company \$1200.00 annually

Company B requires a GFSI Audit sent to BBB company \$1500.00 annually

Company C requires GAP Audit sent to AAA company \$1200.00 annually

Companies D, E, F & G all do in-house document control each charges between \$800-\$3500 annually

Company G requires GAP audit sent to CCC company at \$14.00 per document

ABCD Company hired full-time employee for upkeep (only) \$50,000 annually

Who Pays?

Supplier: Company H has 7 processing facilities.

Received a letter from one document control company hired by Distributer to keep the audits.

**Annual fee required by Company H \$14,520
This supplier sells to 30+ companies.**

Supplier: Company K

Told the document control companies & the customers to go fly a kite, they were not paying.

None of the customers dropped this supplier.

7. Reanalyze

Also known as Validation

Does it control the hazards?

Every 2 years



There is help

- The following organizations working in partnership with FDA have important roles in providing training to the food industry in preparation for implementation of FSMA:

Produce Safety Alliance (PSA)

Food Safety Preventive Controls Alliance (FSPCA)

Sprout Safety Alliance (SSA)

National Institute of Food and Agriculture (NIFA)

National Coordination Center (NCC)

Regional Centers (RCs)

International Food Protection Training Institute (IFPTI)

Cooperative Extension and Land-Grant Universities

Cooperative Agreement Partners

National Association of State Departments of Agriculture (NASDA)

Additional Organizations

Association of Food and Drug Officials

Association of Public Health Laboratories

Association of American Feed Control Officials

Association of State and Territorial Health Officials

Joint Institute for Food Safety and Applied Nutrition (JIFSAN)

FSMA Collaborative Training Forum

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm461513.htm>