



WHOLESALE SUCCESS

www.onfarmfoodsafety.org
www.familyfarmed.org

FAMILYFARMED **USDA** USDA is an equal opportunity provider.

PREPARE YOUR HANDOUTS:

1. FDA Produce Rule Record Keeping Requirements
2. Designated Food Safety Person
3. Traceback and Recall Plan

Welcome to Wholesale Success!

Tools:

1. Manual
2. Food Safety Action Plan Templates
3. Online Food Safety Plan Tool

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WHOLESALE SUCCESS
A Farmer's Guide to Food Safety, Selling, Postharvest Handling, and Packing Produce

Edited by Jim Stone and Atina Duffley

FAMILYFARMED Fourth Edition

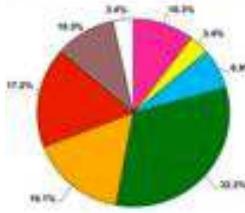
Farmers Are Food Handlers
Responsible For The Safety Of Their Product



Atina Duffley, FamilyFarmed.org trainer, www.atinaduffley.com

Farmers Are Food Handlers

Types of produce Associated with Outbreaks, 1996-2009 (N=87)



Produce Type	Percentage
Berries	46.5%
Green onions	18.2%
Herbs	17.2%
Leafy greens	16.1%
Melons	13.7%
Tomatoes	9.2%
Others	3.4%
Unknown	3.4%

Source: CDC FSA/OPSAH 2010

Produce is linked to 46% of illnesses in outbreaks of single food commodities 1998-2010 -- CDC

Farmers Are Food Handlers

Center for Disease Control and Prevention (CDC)


- 48 M cases of food poisoning (1 in 6 Americans)
- 128,000 hospitalizations
- 3,000 deaths




You are Responsible for the Safety of your Product!

Sources Of Food Borne Illness


1. Physical: such as glass, metal, stones, plastic, bone, or bullets
2. Chemical: such as pesticides, lubricants, or cleaners
3. Biological: such as bacteria, viruses, fungi, or parasites



The most significant carriers of biological contaminants are soil, water and fecal matter.

Food Safety: What Is Changing?

- More at-risk people
 - Elderly
 - Auto-immune diseases/drugs
 - Organ transplants
- Cultural change, more food is eaten raw
- Increasingly complex food distribution
- Lack of resistance from evolving pathogens
- Market expectations and regulations



1938 Federal Food, Drug, and Cosmetic Act (FDCA)

It is illegal to sell adulterated food:

- if the food was “prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health
- is “adulterated” if it bears or contains any poisonous or deleterious substance which may render it injurious to health
- Good Samaritan Laws

History: Good Agricultural Practices (GAPs) and Audits

1998 - FDA's Guide To Minimize Microbial Risks in Fruits and Vegetables (GAPs)


2000s – Over 12 different FS standards developed

2009 - Harmonized GAP Standards
“one audit by any credible third party, acceptable to all buyers”

FDA PRODUCE RULE AND YOUR FARM

Establishes science-based food safety requirements for growing, harvesting, packing, and holding produce on domestic and foreign farms. (first time)

11/2015 Final rule issued
So new, still being interpreted



- Risk based, not as prescriptive as GAPs and 3rd party audits
- Virtually all fresh produce is “covered”
- Primarily deals with biological hazards
- Doesn't require a Food Safety Plan or 3rd party audit (yet)

WILL REQUIRE RECORD KEEPING AND TESTING AND TRACE
Bottom Line: GAPs & FSPs are many buyer's expectation

Food Safety Is Specific To Each Farm


At the most basic level, the rule requires farms to: “take appropriate measures to minimize the risk of significant adverse health consequences or death from the use of or exposure to covered produce . . . and to provide reasonable assurance that produce has not been adulterated.”



1. Risks Assessments – Identify
2. Written Food Safety Plans – Plan Of Action to Minimize
3. Documentation – Traceability

Farmers Are Food Handlers Responsible For The Safety Of Their Product

Exemptions include produce that:



- Is processed with a “kill step.”
- Farms that have an average annual value of produce sold during the previous three-year period of \$25,000 or less.
- Produce for personal consumption.

Putting adulterated food into interstate commerce is a “prohibited act” for ALL farms!

Exemptions include produce that: 

- Is on the exhaustive “rarely consumed raw” list: asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; water chestnuts


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Qualified Exemption and Modified Requirements


- Food sales averaging less than \$500,000* per year during the previous three years; **and**
- More than half of sales are sold to “qualified end-users”.

A qualified end-user is the consumer of the food or a restaurant or retail food establishment that is located:

- in the same state
- or the same Indian reservation as the farm
- or not more than 275 miles away




*adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.

A farm sells \$240,000 in grains, and also has a CSA that grosses \$250,000 selling to members in the same state. 

Is this operation

- Exempt
- Qualified Exempt
- Required to be in full compliance




Putting adulterated food into interstate commerce is a “prohibited act” for ALL farms!

If, however, the farm sells \$250,000 in grain and \$240,000 of produce to a “qualified end user” . . .

Is this operation

- Exempt
- Qualified Exempt
- Required to be in full compliance





Now take a farm selling \$225,000 in produce:

- \$100,000 through a food hub,
- \$75,000 to a local restaurant, and
- \$50,000 to a local grocery store.

Is this operation

- Exempt
- Qualified Exempt
- Required to be in full compliance






Change the grocery to not ~~local~~,

Farm selling \$225,000 in produce:

- \$100,000 through a food hub,
- \$75,000 to a local restaurant, and
- \$50,000 to a ~~local~~ grocery store.

Is this operation

- Exempt
- Qualified Exempt
- Required to be in full compliance



Before we discuss what “qualified exempt” actually means

Is your operation

- Exempt
- Qualified Exempt
- Required to be in full compliance






Qualified Exempt farms are subject to parts of the Rule

- **Subpart A** General Provisions, “QE” and Labeling
- Personnel Qualifications and Training
- Health and Hygiene
- Agricultural Water
- Biological Soil Amendments of Animal Origin
- Domesticated and Wild Animals
- Growing, Harvesting, Packing, and Holding Activities
- Equipment, Tools, and Buildings
- **Subpart O** General record keeping requirements
- **Subpart Q** (Compliance and Enforcement)

It is illegal to sell adulterated food



- **Subpart R** (Withdrawal of Exemption)
- Traceability

Produce Rule Compliance dates

Exempt, or not, what is your compliance date?



Size of covered farm	Time period starting from the effective date of the Produce Rule (Jan 27)	
	for certain specified agricultural water requirements	for all other requirements
Very small business > \$250,000	6 years	4 years
Small business \$250,000 - \$500,000	5 years	3 years
All other business	4 years	2 years

Qualified Exemption Compliance Dates

- 1/27/16 – Compliance date for retention of records supporting eligibility for qualified exemption
- 1/1/20 - Packaging, label, placard indicating farm name and complete address
- 1 year from the general compliance date: Record reflecting that the farm has performed an annual review and verification of continued eligibility for the qualified exemption

1938 Federal Food, Drug, and Cosmetic Act putting adulterated food into interstate commerce is a “prohibited act”, regardless of whether a farm is covered by the Produce Rule or not





MARKET EXPECTATIONS

1. What market demands does your food safety system need to satisfy?

- Do your buyers require a 3rd party audit?
- Can you negotiate with your buyers to accept a risk-based Food Safety Plan or instead of a 3rd party audit?

Bottom Line: Audits & FSPs are many buyer’s expectation



Audit Verification Checklist

- Ask your buyer if they require a specific audit
- Write to the audit
- Do a self-audit

Produce GAPs Harmonized Food Safety Standard
Post-harvest Operations - USDA Checklist




AUDITEE INFORMATION		DDC	C	CAN (AR)	NA	Auditor Comments
Q #	Requirement					
General Questions						
1.1	Management Responsibility					
1.1.1	A food safety policy shall be in place.	WP				
1.1.2	Management has designated individual(s) with roles and responsibilities for food safety functions.	WP				

Jensen Farms Listeria Case

- 33 + 10 dead
- 1 miscarriage
- 147 infected

A truck used to haul culled cantaloupe to a cattle operation was parked adjacent to the packing facility




Six misdemeanor counts of introducing adulterated food into interstate commerce.

Where - How it transferred - How it survived/reproduced

Jensen Farms Facility Design

- Pooling of water on floor adjacent to grading stations and employee walkway
- Floor not easily cleanable;
- Packing equipment not easily cleaned and sanitized
- No equipment to remove field heat before placing in cold storage.

Where - How it transferred - How it survived and reproduced



- Potato packing equipment allowed water to pool
- **No sanitizer was used in the wash water**



Where - How it transferred - How it survived and reproduced

- Conviction based on "strict liability" no need to prove intent to harm
- Primus gave Jensen Farms - 96% a "superior" rating

Prevention of "Listeria Hysteria"

A systematic, well-executed sanitation program with cleanable surfaces will reduce much of the risk.

- Listeria can be found in about 7% of growing areas
- Is hardy and can readily colonize most surfaces.
- Can be transient and gain entry with products, in soil, on shoes, and in dust. An effective sanitation program should be taking care of the Listeria that finds its way in.
- Listeria contaminates cold, wet environments and harbors in drains and on floors and any damp surface if cleaning is not effective.
- Listeria can create bio-films that resist removal.



RISK ASSESSMENT

- Land Use
- Water Quality
- Wild and Domestic Animals
- Worker Health & Hygiene
- Worker Training
- Harvest/Packing/Transport

Written Food Safety Plan, based on a risk assessment to identify potential food safety hazards

"It's a smart business decision"

Where - How it transferred - How it survived and reproduced

Tool: "Action Plans" Combine Risk Assessment, Create A Plan Of Action, A Training Tool, SOPs and Create A "Written Food Safety Plan"

Area of Food Safety System	What	How, When or Frequency	Who	What	Training	Records	Notes (Check for FSP)
1st Barrier - Assess Risk of Pathogens Entering the Plant	Adverse Action by Produce Wash	Wash in the wash tank with sanitizer	Wash Tank Operator	Wash Tank	Wash Tank Operator	Wash Tank Log	Wash Tank Log
2nd Barrier - Prevent Pathogens from Entering the Plant	Wash Tank	Wash Tank	Wash Tank Operator	Wash Tank	Wash Tank Operator	Wash Tank Log	Wash Tank Log
3rd Barrier - Prevent Pathogens from Entering the Plant	Wash Tank	Wash Tank	Wash Tank Operator	Wash Tank	Wash Tank Operator	Wash Tank Log	Wash Tank Log

- There are no requirements for a specific FSP
- FSPs need to be appropriate for your operation
- FSPs can be simple

Food Safety Action Plans and Whole Success Materials

Human Health, Hygiene and Worker Training

- Human Health and Hygiene Action Plan
- Worker Training Documentation
- Sanitary Hand Washing SOP
- Write a Standard Operating Procedure

Sanitation and Cleanliness

- Zone Management
- Sanitation Plan

Water and The Produce Rule

- The Produce Rule and Agricultural Water
- Water Action Plan

Postharvest

- Harvest, Postharvest, and Transportation Action Plan

Record Keeping, Traceability, and Recall Plans

- Traceback and Recall Plan
- Produce Rule Record Keeping Requirements

Land Use and Biologicals

- Land Use Action Plan (LUP)
- Examples for Land Use Action Plan
- Biological Soil Amendments

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Goal - At the end of this training, you will have

- Started your *Land Use Map*
- Filled out *Designated Food Safety Person* document
- Have a good start on creating Action Plans, that include identifying records to be kept and SOPs to be written.
 - Health and Hygiene and Training Action Plan*
 - Land Use Action Plan*
 - Cleanliness Schedule Action Plan*
 - Harvest, Post Harvest, Transportation Action Plan*
- Begun to think through recordkeeping systems you want to use

BREAK-OUT

Fill out "Designated Food Safety Person"

- Designated person needs to be a manager
- On small farms there might not be an alternative

DESIGNATED FOOD SAFETY PERSON

Farm Name _____
 Address _____
 Phone _____

Designated Food Safety Person

Name _____
 Address _____
 Cell # _____
 Phone # at work _____
 Phone # at home _____

Alternate Food Safety Person

Name _____
 Address _____
 Cell # _____

Recordkeeping and Traceability

Good recordkeeping to track profitability, inform decision making.

2002 Bio Terrorism Act

- Where did you get it from?
- Where did you ship it to?

Prepare Your Materials

1. Produce Rule Record Keeping Requirements

Traceback Is Not Recalls

TRACEBACK is a System: an unbroken record of documentation
RECALL is an Action: what you do when there is a problem

Trace"ability"
 T"race"ability
 Traceabi"lity"

Required Reports From Your Business Records

VOLUME OF RECALLED PRODUCT:	BUSINESS RECORDS:
Total quantity PRODUCED DATE produced	None/Yes
Quantity DISTRIBUTED DATE distributed	NO/
Quantity RETURNED	NO/Yes
Estimate AMOUNT REMAINING @ distributor level @ retail level	None/
How is product being GUARANTEED?	None/Yes

Traceback and Recall Plans

Your **Traceback Plan** should demonstrate the ability to trace back and forward by lot through the supply chain.

Buy and Sell? What information do you need to record from vendors?

Field → Grower → Packer → Distribution center → Retailer → Consumer


Trace-forward

Back
 ID, input/production practices, post harvest

Forward
 Who bought, when, how much

Production/Business Records Do Double Duty

- Field maps
- Land history
- Seed lots/source
- Manure/compost
- Harvest records
- Cleaning records
- Sales records
- Worker time cards



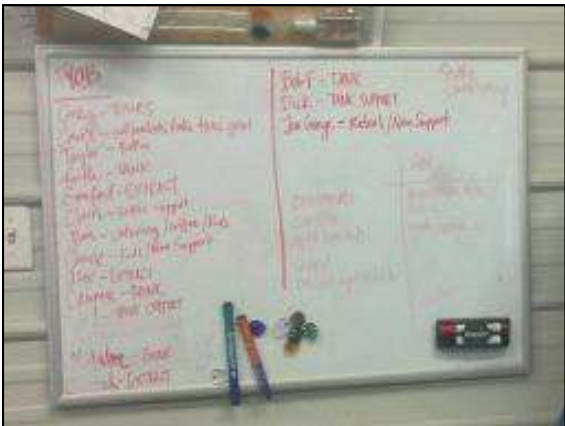
Design Record Keeping for Success

- Avoid duplication
- Document as part of work, not a separate activity
- Instruct staff at the same time as record keeping
- Improve staff performance and accountability



Record keeping needs to be routine – a habit – like brushing your teeth.

DATE	FIELD	HARVEST	POST HARVEST												
			Cleaning			COOLING				STORAGE					
	#	Goal	Actual	Wash	Wash	Wash	Wash	Wash	Wash	Wash	Wash	Wash	Wash	Wash	Wash
2013-05-28	404	75	68	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2013-05-29	404	60	58	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2013-05-30	404	70	68	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2013-05-31	404	80	78	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓





Work With Your Record Keepers' Strengths

Product being washed	Date	Time	Temp F	pH	Pre Test results from dip strip	Conc	act
Green Beans	9/20	9:15 am	85	6.5	70 ppm	Ad	174

29 ACRE

Significantly Raised the Risk of Listeria M.:

- Irrigating fields within three days of harvest
- Cultivating fields within a week of harvest

June 2013

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22

Cornell University

Follow The Money

Ex: Food borne illness can be seed borne

Cleaning Record Strategies

- Utilize service contracts (SOP)
- Create records that instruct

Women's Restroom Maintenance:

Week of _____

1. Check restrooms for cleanliness at the start of the week.

2. Check restrooms for cleanliness at the end of the week.

3. Check restrooms for cleanliness at the end of the week.

4. Check restrooms for cleanliness at the end of the week.

5. Check restrooms for cleanliness at the end of the week.

DETAILED RECORDS ARE CRUCIAL FOR SUCCESSFUL PLANNING

Variety	Sow date	Planting date	Planting #	Spacing	Type	Trans date	Trans #	Harvest date	Sow Record				Harvest Protocol						
									date	date	date	date	date	date	date	date			



Lot Numbers & Traceability

Allows you to trace each specific box/carton :

ON A LABEL:

- Name and address of the farm (phone)
- Commodity
- Variety
- Pack/Size

IN A LOT NUMBER:

- Location of the growing area
- Harvest Date
- Harvest Crew
- Packing Date/Crew
- Shipping Date

Ag Solutions 1000 N. 1st St. Ocala, FL 34471	Product of USA Florida
ORANGES	Lot #: 022208ABC
Valencia	
10 - 4 LB BAGS	
021101810001 5 020 022208ABC	

Lot Numbers & Traceability

Gardens of Eagan LLC
CERTIFIED ORGANIC 952-469-1855
Alissa and Martin Dittley 25498 Eightview, Farmington, MN 55024
Certified Organic by International Certification Services, Holioke, MA 01940

20# Cucumbers

8.16.10 E37 AD 11 8.17.10 AD

Account For Product – One Step Forward / One Step Back

Traceability is a system.

GTIN Number

<http://www.producetraceability.org/>
<https://www.foodlogiq.com/> (free, print on Avery)

Indicator
GS1 Company Prefix
Item Reference
Check Digit

No Food Safety audit programs or regulations REQUIRE a technology based system

Lot Numbers & Traceability

Make sure your traceability system is described in your food safety plan!

• What does GH1 LR 61513 PFM 1 mean?

Production area

Product

Harvest date

Sales outlet

Market date

• Greenhouse #1, Lolla Rosa Lettuce, harvested on June 15, 2013, sold in Palisade farmers' market on June 16, 2013 (1st market of season).

Traceability and Recall Plans

Step 1: Map all production fields or greenhouses, and assign numbers to identify specific growing areas.

Step 2: Using a labeling gun, mark all produce packages with the date and location of harvest.

Step 3: Add the harvest date and location ID on each invoice.

What is working? What is missing?

Where must I store records?

- (a) Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.
- (b) Electronic records are considered to be onsite if they are accessible from an onsite location at your farm.

How long must I keep records?

- At least 2 years past the date the record was created.
- Records to satisfy the criteria for a qualified exemption, (3 years preceding the applicable calendar year) must be retained as long as necessary to support the farm's status during the applicable calendar year.
- Records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued.

The Bottom Line

- **Start with good recordkeeping.** This will help you put traceability into action and enable you to develop a recall plan.
- **Designate one person** to be in charge of your traceability program.
- For smaller-scale production and fewer markets, go low-tech.
- Even if you go high-tech, have a back-up plan for when the printer jams...

FSMA Record Keeping Requirements

Document created 11.21.15 by Anna Duffley and Jo Anne Baumgartner



SUBPART D - GENERAL RECORDKEEPING REQUIREMENTS

Apply to all record keeping requirements, with exceptions for Qualified Exemptions

- The general record keeping standards require records to include:
- Name and location of the farm
 - Actual values and observations collected during monitoring activities
 - An adequate description of the produce applicable to the record (e.g., lot number or other identifier, such as a lot number)
 - Location of the growing area or other area applicable to the record
 - Date and time that an activity was performed or observed.

- The records must be:
- Taken at the time an activity is performed or observed
 - Must be accurate and legible
 - Must be dated and signed by the person doing the activity

BREAKOUT

1. On the FSMA Record Keeping Requirements document, identify what Produce Rule required records you already are keeping.
2. Are there other records you want to keep?
3. For records not being kept,
 - identify which you want to add keeping
 - is there a system already it could be added to?
 - what system do you want for keeping it?

FSMA Record Keeping Requirements
Document created 11.21.15 by Anna Duffley and Jo Anne Baumgartner on the just released Produce Rule

SUBPART D - GENERAL RECORDKEEPING REQUIREMENTS
Apply to all record keeping requirements, with exceptions for Qualified Exemptions

The general record keeping standards require records to include:

Your Recall Plan should clearly define responsible parties and critical actions in the event of an incident.

Establish Procedures:


1. Who is in charge: names, contact info and duties
2. Description of lot tracking system
3. Timeline and process for alerting buyers
4. List of resources with contact information: buyers and suppliers, St Health Dep, St Ag Dept, extension, media, testing labs, lawyers, medical personnel, grower association available to help

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Two Volunteers Please To The Front Of The Room

Mock Recall – Day 1



- how simple a mock recall can be
 - can serve as a relationship building tool
 - demonstrates the importance of trace systems

Mock Recall – Day 1 Penn State Extension 2012



Grower: “Will you help us out by participating in this year’s mock recall exercise? This is NOT a real recall. We are just tracking some of our product to check our traceability.”

Buyer: “Sure! Of course! WOW! I wish all our growers had traceback and recall plans. How does a mock recall work?”

Mock Recall – Day 1 Penn State Extension 2012




Grower: “We’ll make our usual shipment to your store tomorrow. The day after, I’ll call you and ask how much of that shipment is still at your location.”

Buyer: “Ok, we’ll be ready for you.”


Mock Recall – Day 2 Penn State Extension 2012

There are two parties in this transaction – they both have duties



*The produce is shipped by the grower
 The product is received by the buyer*

Mock Recall – Day 3 Penn State Extension 2012



Grower: “Hello, this is _____ from ___ farm. Calling about the **MOCK** recall exercise.”

Buyer: “Hi. Thanks for setting up this process. What’s next? By the way, that was beautiful produce you sent.”

Mock Recall – Day 3 Penn State Extension 2012

Grower: Thanks! Could you tell me how many boxes you have already sold and how many remain at your location? The lot number on the box label is PFS2015WALLACE”

Buyer: “Sure. According to our records, we received 20 boxes, sold 12 and have 8 on site.”

Mock Recall – Day 3 Penn State Extension 2012

Grower: Thank you. Would you please email this to me for my records on your letterhead and date it?

Buyer: Of course. Thank you! I really appreciate that you have good traceability and a recall plan. I like doing business with you.

Keep a record of the mock recall!

Mock Recall Log

Mock Recall Log

Name: _____

Buyer Name/Company: _____

Date: _____

Inventory Information		Shipping Information			Mock Recall Information		
Product/Description	Case Count	Case No.	Lot No.	Case No.	Case No.	Case No.	Case No.

Print this record

Print your confirmation (includes name and address)

Name: _____

WHOLESALE SUCCESS

THANK YOU!

- Resources
- Follow-up

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