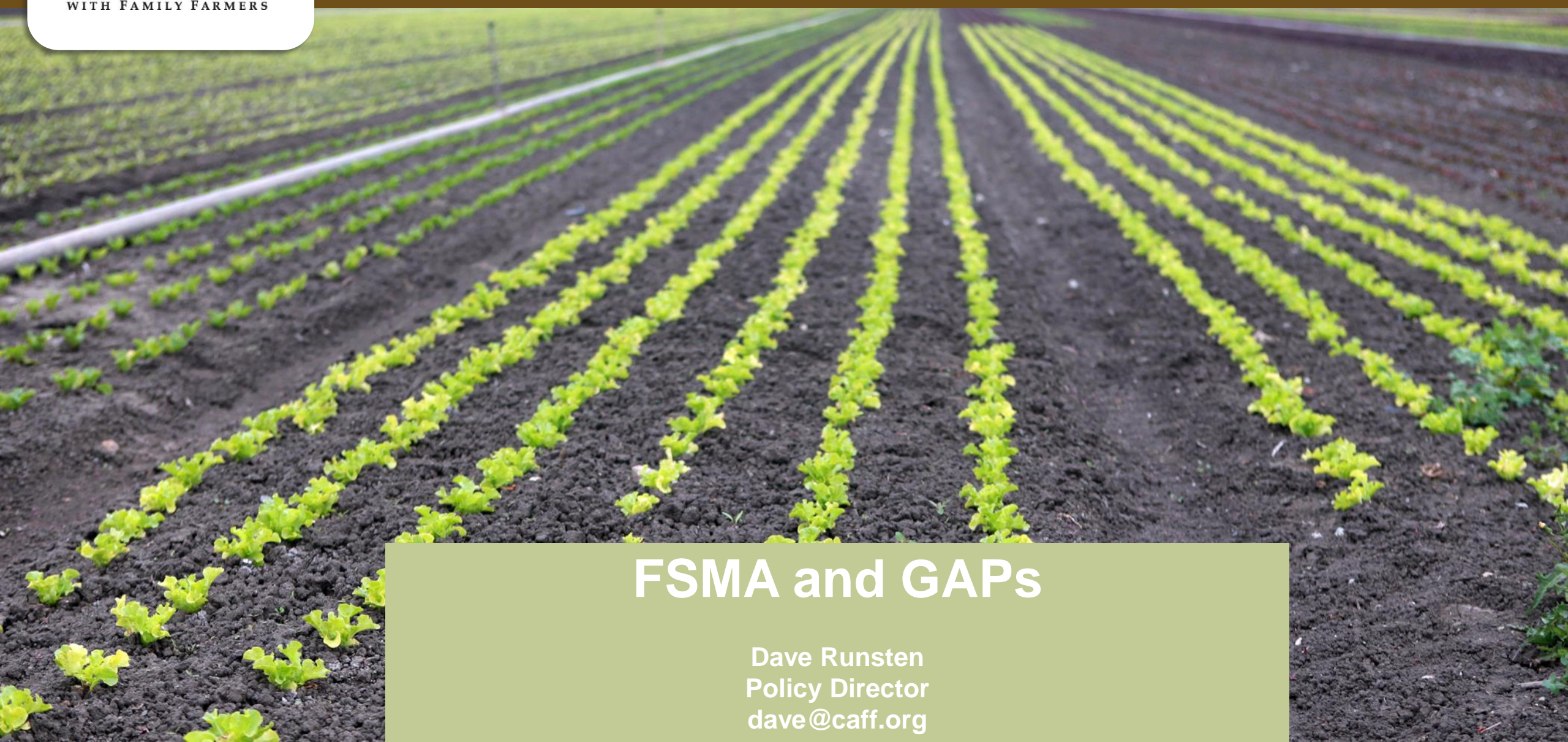




Community Alliance with Family Farmers



FSMA and GAPs

Dave Runsten
Policy Director
dave@caff.org

What does FSMA cover?

- **FDA Produce Rule—Exemptions**

- Produce that is NOT covered by the Produce Rule includes:

- Produce grown for personal or on-farm consumption
- Produce that is rarely consumed raw (e.g, potatoes, turnips, winter squash)
- Produce that is not in its raw or natural state (i.e., produce that receives additional processing sufficient to kill pathogens and that would be subject to the Preventive Controls rule)

- You are NOT covered by the Produce Rule if the average annual monetary value of produce you sold during the previous 3-year period is no more than \$25,000 (in inflation adjusted 2011 dollars)



FDA's List of Produce Rarely Consumed Raw

Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.



Tester-Hagan Qualified Exemption

- A farm is eligible for modified requirements through a qualified exemption if the farm:
 - Has less than \$500,000 in annual gross sales (2011 dollars adjusted for inflation) over a previous three-year period, AND
 - Sells the majority of the food directly to a “qualified end-user,” i.e., a consumer, or a restaurant, or a retail food establishment (e.g., a grocery store, not a distribution center) that is located in the same state as the farm or not more than 275 miles from the farm.
 - The \$500,000 threshold applies to the value of all food sales from a farm, not just sales of covered produce. This includes sales of processed foods, hay, commodities like corn and soybeans, dairy, livestock, and produce.



Tester-Hagan Qualified Exemption

- What does \$500,000 in constant 2011 dollars mean?
- Due to inflation, every year a sum of money is worth less. So we use a deflator, a measure of inflation, to account for this.
- Using the FDA-approved Implicit GDP deflator, we see that in 2011 prices rose 1.8%, in 2012 they rose 1.6%, 1.6% in 2013, and 1% in 2014. So by 2015 \$500,000 in 2011 was worth \$530,672. In 2015, the three year average would have been \$524,412.
- The FDA will calculate and distribute these numbers, but you need to keep them in mind when you calculate a rolling 3-year average of your total gross sales.



Tester-Hagan Qualified Exemption

- If you meet the requirements for a qualified exemption, then you still must:
 - Provide the name and complete address of the farm where the produce was grown on either a food packaging label or on a sign at the point of purchase (such as a farmers' market or CSA box or farm stand or on the internet);
 - Keep records that justify your exemption, such as total sales and sales to qualified end users (e.g. sales receipts). You must start keeping these records on March 25, 2016. You must keep these so FDA could inspect them within 24 hours. They must be detailed and signed or initialed by the person doing the recordkeeping. They can be written or electronic.
 - Comply with the compliance and enforcement requirements of the Produce Rule, i.e. you are not exempt from FDA oversight and the prohibition on putting adulterated food into commerce; and
 - Be subject to the provisions regarding the withdrawal of your status as a partially covered (“qualified exempt”) operation.



Timeline for Compliance

- Farms grossing more than \$500,000 in produce sales annually (calculated by a 3 year rolling average in 2011 dollars)
 - January 26, 2018
- Farms grossing more than \$250,000 but less than \$500,000 in produce sales annually
 - January 26, 2019
- Farms grossing less than \$250,000 but more than \$25,000 in produce sales annually
 - January 26, 2020
- Farms that do not qualify for an exemption or a qualified exemption have an additional two years to comply with water testing requirements

Do I Need a Food Safety Plan?

- FMSA does not require a food safety plan, nor does it require a third party audit. However, if you are subject to FSMA then you must comply with the rules.
- California laws do not require a food safety plan nor a third party audit. Direct marketing laws require you to implement GAPs:
 - AB 224 (2013) CSA Law
 - AB 1871 (2014) Farmers Markets
 - AB 1990 (2014) Community Food Producers (Urban Gardens)
- Buyers may still require a food safety plan and/or a third party audit
- Insurance Companies may also
- We encourage a plan



Do I Need to Register with FDA?

- If you are only growing, harvesting, packing, and holding produce, you do not need to register
- If you are packing produce from other similar farms, such as in a multi-farm CSA, you do not need to register
- If you are processing food, you may need to register, depending on what you are doing. This is a separate rule, the Preventive Controls rule
- If you are drying fruit, that is considered part of being a “farm” and you do not need to register, but if you are making cheese or almond butter you do



Do I Need to Register with FDA?

- A farm or a group of farms can have a secondary farm facility where they wash, pack, hold produce and this facility does not need to register if a majority of the produce comes from these farms and these farms own a majority of the business
- Food retailers and restaurants are exempt from registering and a CSA, farmers market, farm stand are considered food retailers (not finalized)
- In general, if you do activities on your farm that do not fall under FDA's definition of a farm, then you are a farm mixed-type facility and you must register



Who is subject to Preventive controls?

- FDA has a long list of food processing activities that they consider low risk
- If you are a farm mixed-type facility and you only process the food that FDA considers low risk, and you are a small (employs fewer than 500 FTE employees) or very small (less than \$1 million in sales) business, and all of the processing takes place on your farm, then you are exempt from the new Preventive Controls requirements (e.g. HARPC), but you are expected to follow current good manufacturing practices and you are subject to record keeping and training requirements.



Who is subject to Preventive controls?

- Even if you process food that FDA does not consider low risk, if you have less than \$1 million of sales of all human food, then you are a “qualified facility” and not subject to the full Preventive Controls (e.g. HARPC).
- However, you still have to follow good manufacturing practices, keep records, and regularly submit attestations that you meet the requirements to be a qualified facility and that you are either following state and local laws that regulate your production or that you are following some plan of identifying hazards, implementing preventive controls, and monitoring.



What are GAPs?



- GAPs = Good Agricultural Practices
 - 5 key areas of Focus:
 1. **Water**
 2. **Employee Training (Health & Hygiene)**
 3. **Land Use & Animal Access**
 4. **Equipment, Tools & Buildings**
 5. **Manure, Compost & Chemicals**
 - Start by understanding your practices and the potential risks associated with them
 - Identify what you could do to minimize any identified potential risks

****No such thing as “Zero-Risk”****

What are GAPs?

FARM RISK ASSESSMENT

Farm Name: _____

Date: _____

Farm Location: _____

Completed by: _____

If the answer to the question falls in the shaded box, a Corrective Action is needed to demonstrate what is done to minimize the risk of contamination. (Corrective Actions examples: monitoring, policies, training, covering items, cleaning, etc....)

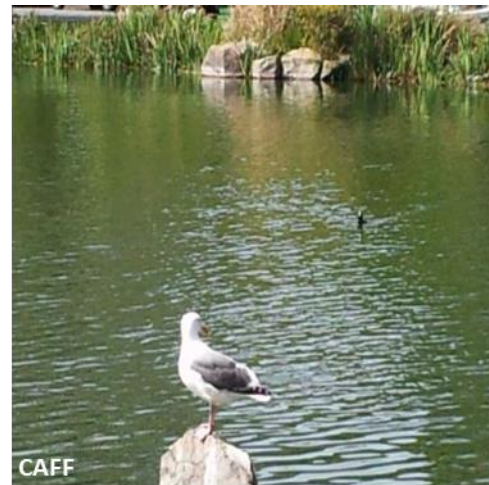
	YES	NO	N/A	Corrective Action
LAND USE (History & Adjacent)				
Has the land previously been used for mining, animal husbandry, industrial or waste storage purposes?				
Are septic tanks/fields, waste disposal and drainage systems well-constructed and maintained?				
Are there any water bodies (creek, irrigation/drainage ditches, river, slough) running through your property?				
Do animals/livestock have direct access to water bodies on your farm?				
Are there any water bodies (creek, irrigation/drainage ditches, river, slough, lakes) adjacent to your property (including in neighboring properties)				
Do animals/livestock have direct access to water bodies on your property and/or adjacent properties?				
Has this property flooded in the last year?				
Does activity on adjacent land to growing area pose a risk to crop(s) or water source(s)?				
Are there measures in place (barriers, drainage, setbacks, buffers, hedgerow, windbreaks etc...) to minimize drift or leaching of manure, poultry dust, or pesticides from adjacent farms?				
WATER				
Is each water source that comes in direct contact with crop or with crop contact surfaces tested for fecal coliforms / generic E.coli? (Including water used for chemical application.)				





1. Water

- Understand your source(s), use and potential contaminants
 - Where is your water coming from?
 - Is it used directly from the source or stored?
 - What is it being used for?





1. Water



- Evaluate water risk(s) - know the quality of your water source(s)
 - Test water for generic E.coli
- Understand activities occurring on your property, adjacent property and upstream that could potentially contaminate your water source(s)



1. Water



- Minimize Risks of Water contamination by:
 - Converting to drip irrigation (if feasible)
 - Ensuring well is properly maintained
 - Increasing (maximize) time intervals between irrigation and harvest
 - Exposure to UV kills bacteria
 - Using potable water close to harvest
 - Chemical performance may be impacted by water quality



1. Outbreaks linked to Water Contamination

- Salmonella outbreak in tomatoes in Virginia
 - Associated with a pond used for irrigation
- Cyclospora outbreak in Guatemalan raspberries
 - Associated with water for chemical application
- Shigella outbreak in BC, Canada spinach
 - Associated with septic leakage contaminating wash water (surface water source)





2. Employee Health & Hygiene Training

**Wash hands
before returning
to work**



**Lávese las manos
antes de regresar
a trabajar**

- Proper training & education can minimize the risk of contamination
 - Good personal hygiene practices
 - Good harvesting practices
 - Field cleanliness
 - Reporting problems
 - Moving between animal fields, barns & crop growing areas





2. Employee Health & Hygiene Related Outbreaks



- 1994 California Green Onions – *Shigella* – 72 cs reported
 - The spread of *Shigella* can be stopped by frequent and careful handwashing with soap and taking other hygiene measures.
- 1997 California Strawberries - Hep A Virus - 250cs reported
- 1998 US Green Onions – Hep A Virus – 43 cs reported
 - **Hepatitis A** is a liver infection caused by the Hepatitis A virus (HAV). Hepatitis A is highly contagious. It is usually transmitted by the fecal-oral route, either through person-to-person contact or consumption of contaminated food or water.



2. Employee Health & Hygiene Training Materials & Log

Employee Training Policy & Instructions

<p>Employee Illness, Disease and Injury</p> <ul style="list-style-type: none"> <input type="radio"/> Persons able to transmit, or suffering from, a contagious disease and/or illness transferable to food (e.g., Hepatitis A, Salmonella, <i>E. coli</i> O157:H7) and those with a temporary illness (e.g. diarrhea, nausea or vomiting) are advised to see a doctor & stay at home <input type="radio"/> Employees are trained on the role and responsibility they play in preventing the contamination of crops <input type="radio"/> Open wounds are immediately treated and covered with a waterproof dressing (e.g. rubber gloves) <input type="radio"/> Report illnesses and injuries as soon as they occur 	<p>Employee Hand Washing</p> <ul style="list-style-type: none"> <input type="radio"/> Hands are washed: <ul style="list-style-type: none"> - Before beginning work each day - Before entering the harvesting area - Before putting on gloves (if used) - After every visit to the restroom - After breaks, meals, smoking - After hand-to-face contact (e.g., coughing, sneezing, blowing nose) - After applying sunscreen and insect repellent - After using the phone - After handling garbage <input type="radio"/> Hands and reusable gloves are washed using proper hand washing techniques: <ul style="list-style-type: none"> - Wet hands - Lather with soap - Scrub well (20 secs) - Rinse - Dry hands with paper towel <input type="radio"/> Gloves are not worn as a substitute for hand washing
<p>Employee Glove Use</p> <p><input type="checkbox"/> Check if gloves are <u>not</u> used & proceed to the next sub-section</p> <ul style="list-style-type: none"> <input type="radio"/> Gloves are made of rubber, nitrile, polyethylene, polyvinyl chloride, polyurethane or cloth <input type="radio"/> Hands are washed, before gloves are put on and after they are removed <input type="radio"/> Gloves are replaced when ripped or worn out <input type="radio"/> Gloves are removed when leaving the work area and replaced upon return or, if reusable, washed (using proper hand washing technique) after being put back on 	<p>Other</p> <ul style="list-style-type: none"> <input type="radio"/> Employees adhere to the following: <ul style="list-style-type: none"> - Always use toilet facilities - Never spit in the crop growing area - Only eat, smoke, drink, chew gum, spit or use tobacco products in areas designated to these activities - Put personal effects in designated areas (ie. weatherproof clothing, boots, lunches etc...) - Use garbage cans - Leave tools in designated areas (including
<p>During Harvest</p> <ul style="list-style-type: none"> <input type="radio"/> Only harvest using clean tools, equipment & into clean containers <input type="radio"/> Always inspect to ensure there is no wildlife or animal contamination (ie. droppings / trampling) <input type="radio"/> Product contaminated with blood is discarded 	

Employee Training Log // Registro de Entrenamiento de los Empleados

Date // Fecha:	Trainer // Instructor:	Subject/Topic: // Sujeto/Tema
	Print Employee Name // Nombre del Empleado	Employee Signature // Firma del Empleado



2. Employee Health & Hygiene Training Cleaning Logs

Toilet & Hand Washing Cleaning Log

Date & Time	Toilets				Hand Wash Station				Comments / Observations:	Checked by:
	Cleaned		Restocked		Cleaned		Restocked			
	Yes	No	Yes	No	Yes	No	Yes	No		



3. Land Use & Animal Access



- Property Use & Issues
 - Previous use
 - Flooding
- Adjacent sites
 - Practices & Use
 - Upstream
 - Downwind
 - Buffers, Set backs or Windbreaks
 - Slopes & Gradients





3. Land Use & Animal Access

Domestic & Wild Animals

- Do animals have access to crop area, packing area, water source(s), manure/compost?
- Biodiversity is essential, but look for signs of contamination:
 - Trampling of product
 - Feces / Droppings—don't harvest contaminated plants
 - Flocks of birds moving from feedlots or garbage dumps to crop area
- Domestic Animals should be kept out of growing areas
 - Records for animal rotations in field





3. Land Use & Animal Access



- To minimize potential risks:
 - Monitoring & visual inspection before harvest
 - Create a policy EXAMPLE:
 - In the event that feces or carcass are found in the produce growing area, the area around the feces or carcass will be marked or flagged and:
 - The area (roughly “X” ft buffer) around the contamination site will be marked off with caution tape. Crops in this area will not be harvested for at least “Y” days. The harvestable produce in the marked area along with the feces/carcass will be collected in trash bags with disposable gloves and tools and deposited in the county land fill dumpster.
 - If there are more than “Z” days prior to harvest, the feces or carcass will be collected with appropriate gloves, tools and trash bags and deposited in the county land fill dumpster.



3. Animal Access Contamination Linked to Produce

- 2011 Fresh Strawberries *E.coli* 0157:H7 at Oregon's Jaquith Strawberry Farm: (15 total ill, 7 hospitalized and 1 death of elderly)
– Wildlife--specifically deer feces--was isolated as the source.

(Note: Deer feces in California have NOT been found to have *E.coli* 0157:H7)



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3. Land Use & Animal Access Monitoring/Record Keeping

Pre-Harvest (GAPs) Checklist ("No" answers require a corrective action)

Crop(s) Inspected:	Date:
	Checked by:
Farm Location & Blocks:	

INSPECTION	YES	No	NA	CORRECTIVE ACTION
ADJACENT LAND USE				
Activity on adjacent land does not pose a risk of contamination to the growing area				
SITE				
Flooding has not occurred so far this season either natural or irrigation related				
No strange or suspicious activity is observed (broken gates/locks, unusual tire tracks etc...)				
Growing area is free of animal (wild & domestic) intrusion including droppings, carcasses, tracks, trampling etc...				
The site is free of excessive garbage				
WATER				
A tested safe water source is used for chemical				



4. Equipment, Tools & Buildings



- Understand how harvest tools, equipment & containers are:
 - Cleaned
 - Used
 - Stored
 - Adjusted / Adapted / modified from original intended use





4. Equipment, Tools & Buildings



- What are the buildings being used for?
 - Storage
 - Is the building sectioned off?
- How is the risk of cross contamination minimized?
- Packing Area –
 - Is there a flow of product movement?
 - Are employees trained to identify risks?
 - Is pest monitoring occurring?
 - Can it be easily cleaned? Including:
 - All produce contact surfaces
 - Drains
 - Using shatterproof lights / light covers?





4. Equipment, Tools & Buildings



- Minimize risk of contamination
 - No direct ground contact
 - Proper storage
 - Covering boxes
 - New liners in used boxes

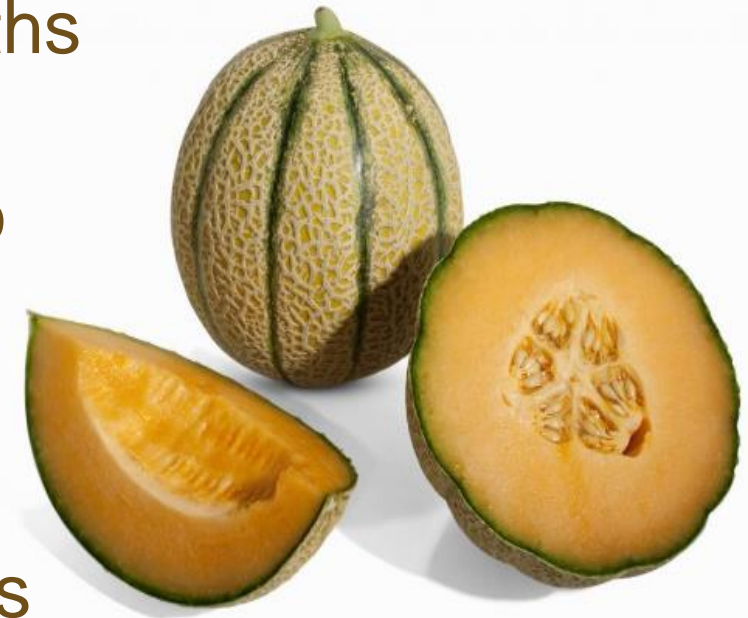




4. Equipment Contamination Linked to Produce



- 2011 Multi-state Cantaloupe Listeria
- 147 illnesses reported in 28 states, with 33 deaths and 1 miscarriage
- Isolated to a potato washer that was modified to clean melons
- First time that farmers faced criminal charges
- The Jensens (2 brothers) were sentenced in January 2014 to five years probation, six months home detention, and \$150,000 each in restitution fees to victims





4. Equipment Cleaning Log



General Cleaning & Sanitizing Log

Date	Describe or Name Equipment/Tool/Containers	Cleaned*		Sanitized		Product Used & Amount Used		Cleaned by:
		Yes	No	Yes	No	Cleaner	Sanitizer	



4. Equipment Cleaning Schedule



- Sample of a Cleaning Schedule

		Daily	Weekly	Every 15 Days	Monthly	Quarterly	Yearly
Harvest Knives	Washed		x				
	Sanitized		x				
Harvest Crates	Washed	x					
	Sanitized				x		
Crop Wash Tub	Washed	x					
	Sanitized		x				
Employee Drinking Water Cooler	Washed		x				
	Sanitized		x				
Ground Contact Crates	Washed						x
	Sanitized						x
Field Truck	Washed				x		
	Sanitized					x	
	Swept	x					
Delivery Truck	Washed				x		
	Sanitized				x		
	Swept		x				
Garbage Cans	Washed					x	
	Sanitized					x	



5. Manure, Compost



- Used to help build up organic matter and add some nutrients to soil

Understand -

- Source/type
 - Raw/Composted
 - Certificate of Analysis / Records for compost
 - FDA now has rules for making your own
- Application Method
 - Injected / Broadcasted
 - Incorporated / Side dressed





5. Manure, Compost

- Application Timing
 - Prior to planting / After harvest
- Storage
- Cross Contamination





5. Chemicals



- Storage:
 - Locked/secure place with limited access
 - According to chemical category (especially for restricted chemicals)
 - Dry chemicals above liquid
 - At least 100 ft from well
 - Vented to the outside
 - Away from crop storage area / food contact containers
 - Off the ground & shelves/ground should be sealed to prevent absorption (especially for restricted use)
 - With **legible labels** & according to label



5. Chemicals

- Use according to label & only when needed follow IPM
 - EPA registered for use on crop & target pest
 - Follow **Re-Entry Interval (REI)**
 - Understand **Pre-Harvest Intervals (PHI)**
 - Restricted Use = Applicators License Needed
 - Calculate the rate & quantities to prevent left over
 - Dispose of excess chemical and its container in accordance with label directions and local regulations





5. Chemicals



- Safety

- Protective equipment and clothing, according to label instructions.
- Do not apply pesticides during very hot weather or in windy conditions.
- Wash skin and clothing if spills occur and after applying chemicals.
- Do not smoke while working with chemicals.
- Post chemical application information so employees know when and where it is safe to work with a crop after a chemical application

- Equipment

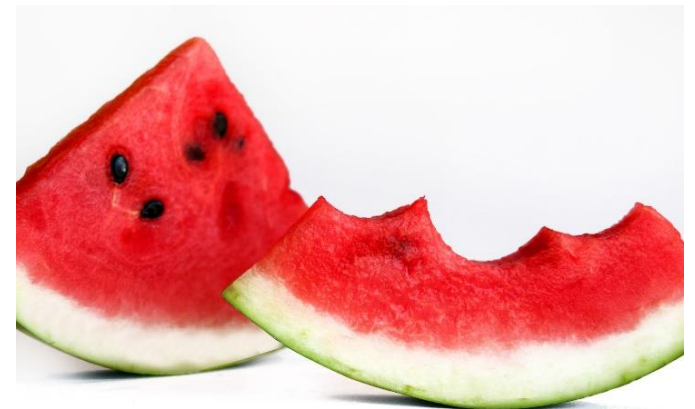
- Calibrate at least annually (keep records)
- Clean regularly – including nozzles to prevent blockage / excess
- Ensure pressure gauge is working properly



5. Manure & Chemicals Contamination linked to Produce



- E. coli 0157:H7 outbreak in shredded lettuce in California
 - Associated with irrigation water from well that was contaminated with dairy lagoon water
- 1985 – Banned insecticide (Aldicarb) used on watermelons by growers in San Joaquin Valley
 - 2000 + reported sick, 17 hospitalized, 6 deaths & 2 stillbirths (<http://www.environmentalhealthnews.org/ehs/news/aldicarb-phaseout>)





5. Manure/Compost & Chemicals Record Keeping



Soil Amendment Log

DATE	FIELD / BLOCK	WHAT IS APPLIED	METHOD OF APPLICATION	RATE OF APPLICATION	APPLIED BY	HARVEST INTERVALS TO OBSERVE			ADDITIONAL COMMENTS / OBSERVATIONS
						90 Days	120 Days	NA	
Date of application	This field or block should be the same as on your field site map	Type of amendment. Compost? Manure? Gypsum? Fish meal? Etc....	How it is applied. Sidedressed? Broadcasted? Etc...	The more specific the better but general is ok Ex. 2 tons/acre	Who applied it or who oversaw the application	Manure used on crops not touching ground	Manure used on crops touching ground	Compost	



5. Manure/Compost & Chemicals Record Keeping



Pesticide Application Log

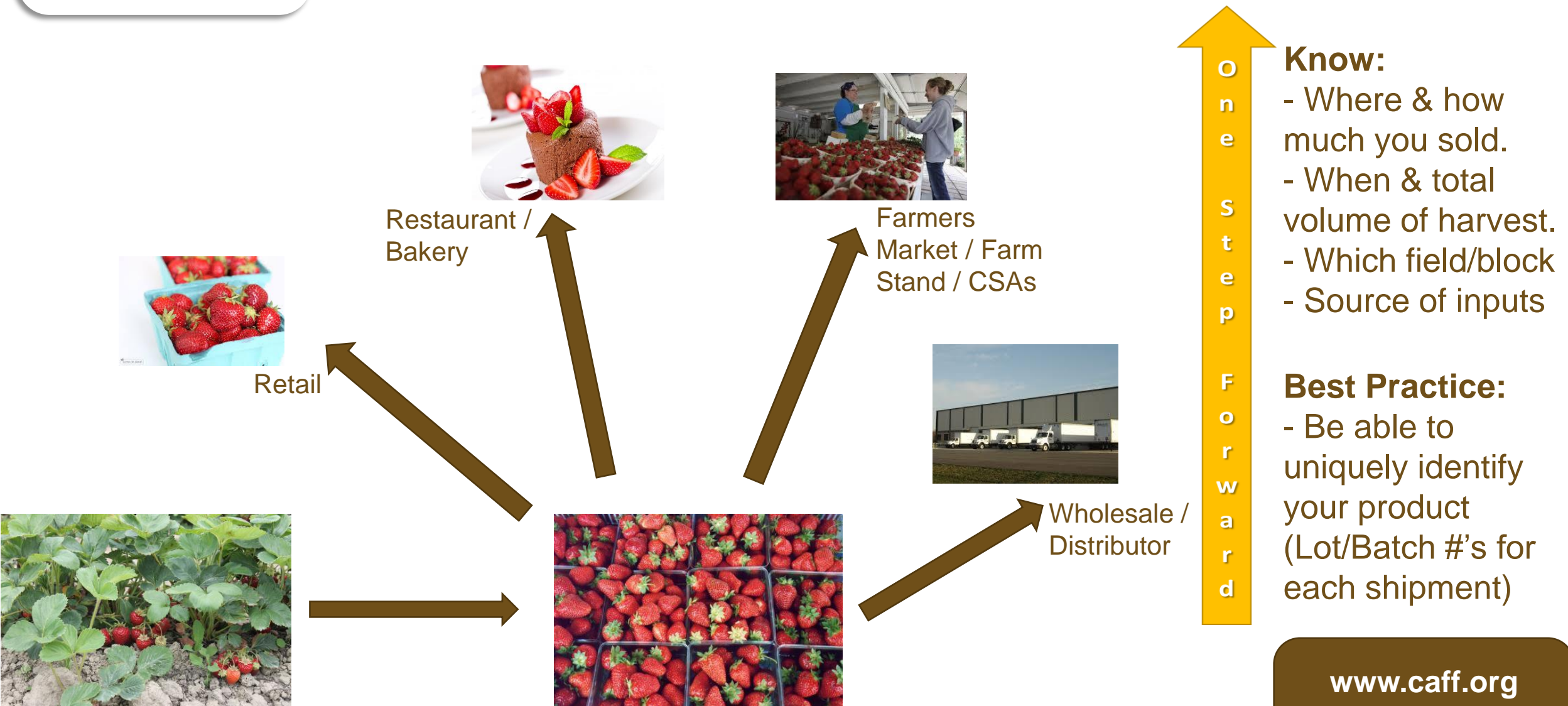
Farm Name:							Field Street Address:							
Date of Application	Field(s) / Block(s) Treated	Crop(s) Treated	Total Acres Treated	Pesticide Name	EPA Registration Number	Active Ingredient	Problem / Pest Being Treated	Pesticide Concentration Used	Water Used	Total Volume Applied	Time of Completion	Time & Date of Allowed Re-Entry	Pre-Harvest Interval (PHI)	Applicator Name / License & Handler #
5/15/15	T: 1 - 4	Tomatoes	8	Vydate L	352-372	Oxamyl	Aphids & Mites	2 pints / acre = 16 pints	20 gallons / acre = 160 gallons	160 gallons	9:30 am	9:30 am 5/17/15	3	Jane Smith CO11111

On Farm Traceability



- One step forward (where it was sold) and one step back (where it was grown)
- Why is it important?
 1. Being able to identify contaminated product & its distribution
 2. Limiting the scope of recall
 3. Limiting financial consequences
 - (Ex. Losing \$ from one field of a crop/grower vs losing all the fields of a crop/an industry)

On Farm Traceability



On Farm Traceability

Interviews

PLU's # /
Item #

Wholesale /
Distribution #

Farm / Field / Block



Retail

Institution

Market



One Step Back



On Farm Traceability Record Keeping is Essential






Harvest Log

Date mm/day	Crop Harvested	Field / Block	Total # of Units / Weight sold	Individual Unit size (ie. 20lb/box)	Where the Crop is Sold					For CSA / Farmers Market Specify location(s) & date	Completed By
					FM	CSA	WS	RT	FS		
08/10	celery	R-3	40 CS	12 bunches / cs				✓			J.Doe
08/10	zucchini	R-1	20 CS	20 lbs / cs			✓				J.Doe



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Dave Runsten
CAFF Policy Director
dave@caff.org

www.caff.org