Good Agricultural Practices and the FSMA Produce Safety Rule

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Outline

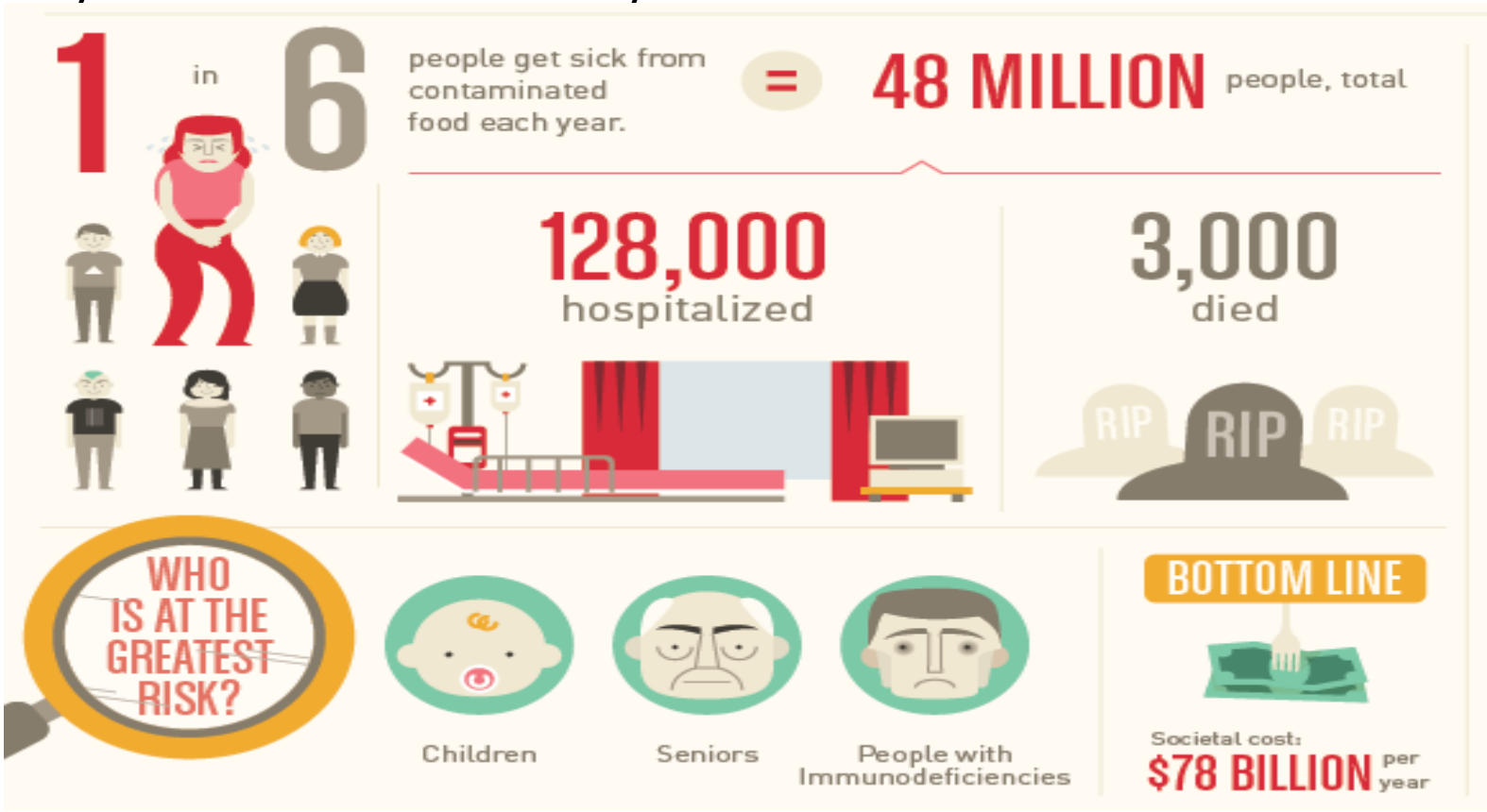
- Importance of Food Safety
- GAPs vs. FSMA vs. Audits
- Produce Safety 101
  - Key Requirements of FSMA Produce Safety Rule
  - GAPs to Implement

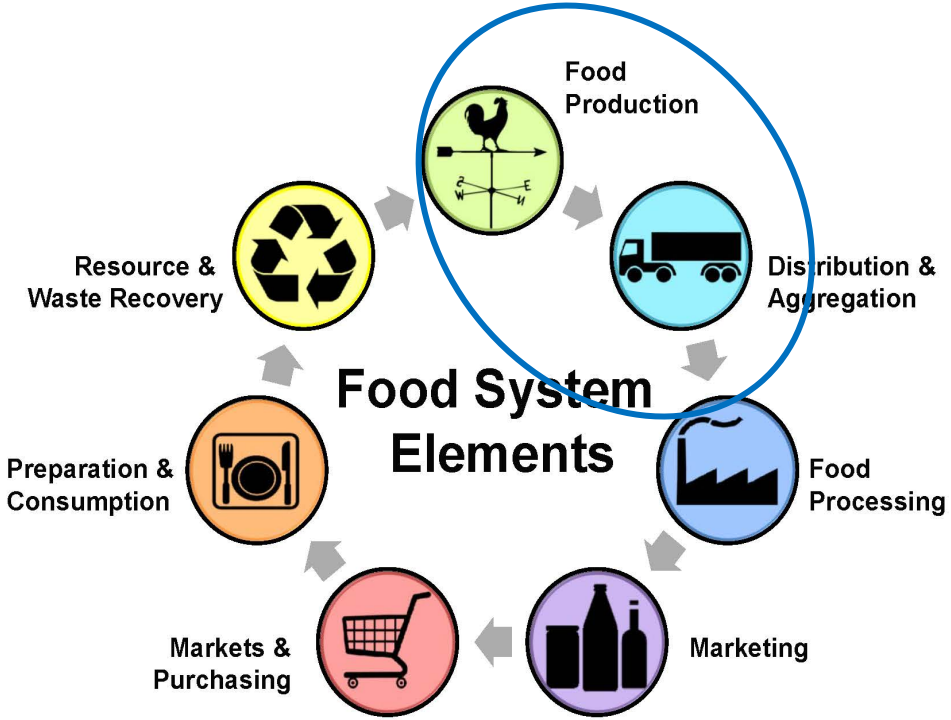
Consumer Trends

- Increase produce consumption
- More interest in consuming produce **raw**
- Food as medicine

Food safety is a public health concern

Why Farm Food Safety?



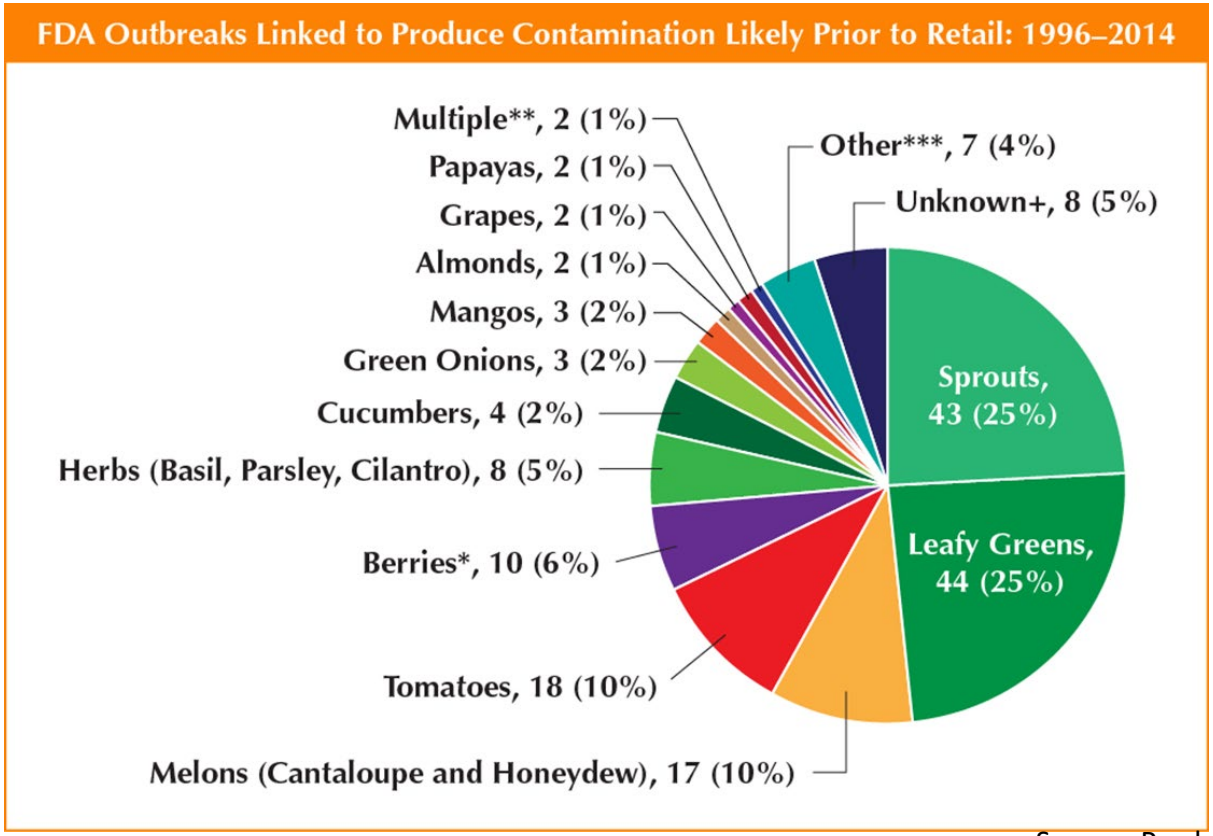


Everyone has a role in food safety!

- Growers
- Packers
- Aggregators, Food Hub
- Wholesalers
- Retailers
- Farmers markets
- Restaurants
- Consumer

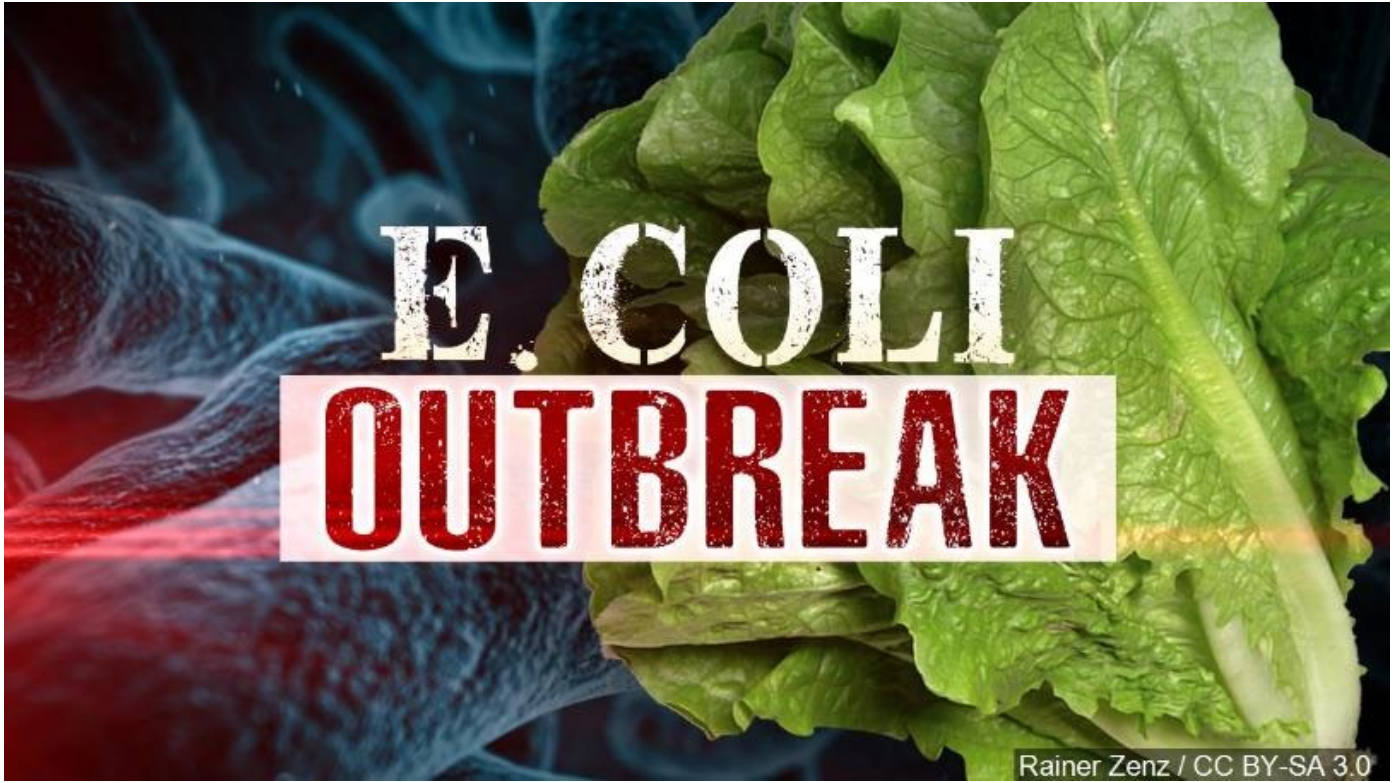
Adapted by Christy Shi, Center for Environmental Farming Systems.
From: Wilkins, J. and Eames-Sheavly, M. Discovering the Food System; An experiential learning program for young and inquiring minds. Cornell University, Departments of Nutritional Science and Horticulture. http://www.discoverfoodsys.cornell.edu/

Produce Related Outbreaks



Source: Produce Safety Alliance

Produce Related Outbreaks



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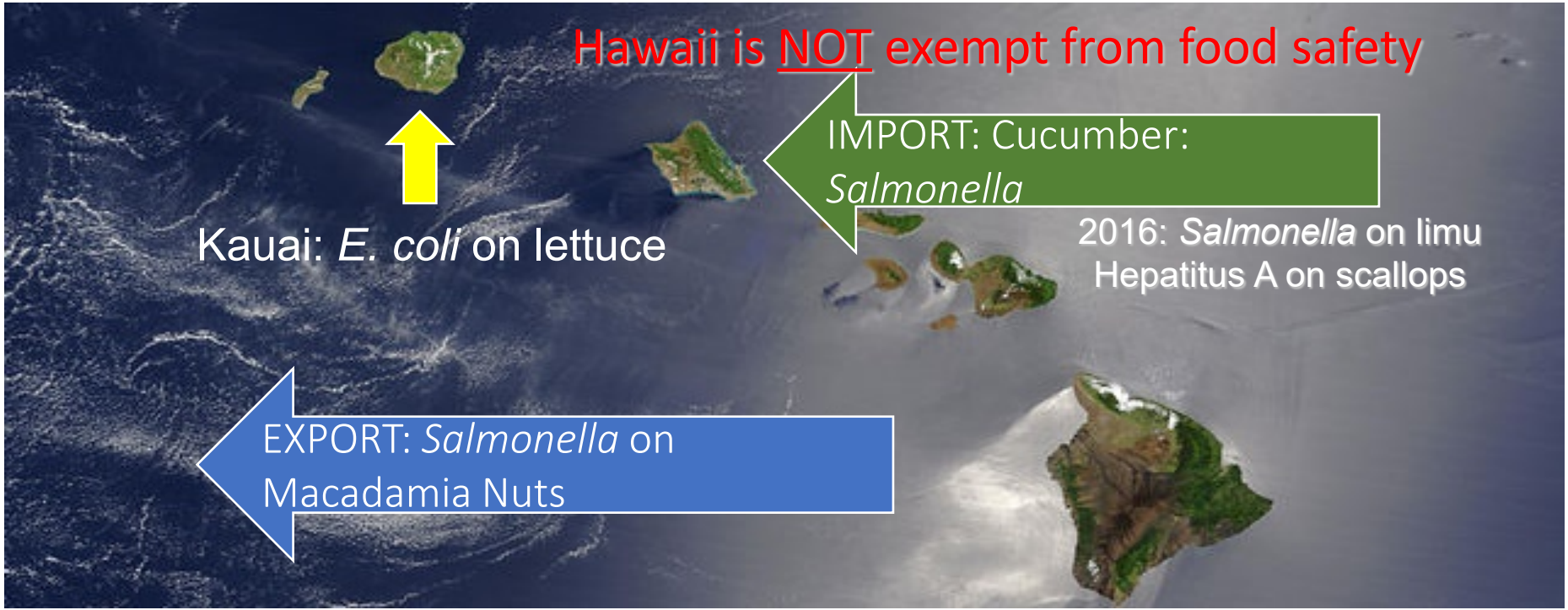
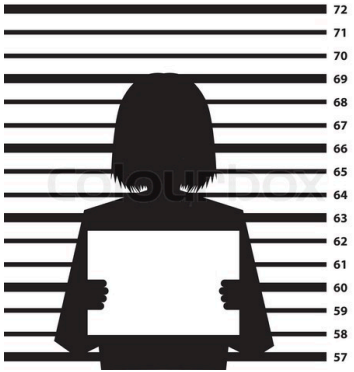
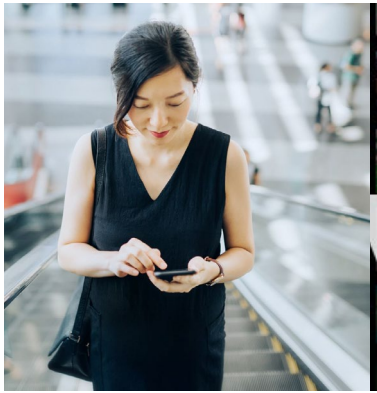


Slide from Sugano 2016

How can this affect a farmer?



- Recalls
- Bad publicity
- Loss of customers and trust
- Lawsuits
- Fines
- Prison time



Navigating the farm food safety landscape

Audit?

Produce Safety Rule?

FSMA?

Inspection?

"Food safety certified"?

FSMA vs. GAPs vs. Audits

May be voluntary + added requirements

Mandatory

3rd Party Independent Audits
Primus, NSF, USDA AMS, HDOA, etc.
(May be voluntary, but often required by buyers, farmers markets, and distributors)

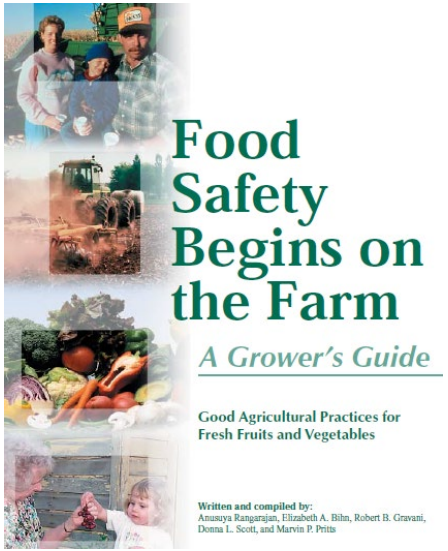
Food Safety Modernization Act
USDA FDA

Good Agricultural Practices (GAP)
USDA FDA (1998)
Educational

Good Agricultural Practices (GAPs)

- FDA guidance on growing fresh fruits and vegetables
- Established in 1999 by funding provided by the USDA and FDA
- GAPs-PSA based at Cornell University
- GAPs program has collaborators in 34 states, including Hawaii

- Preventative, science and risk-based reduction guidelines

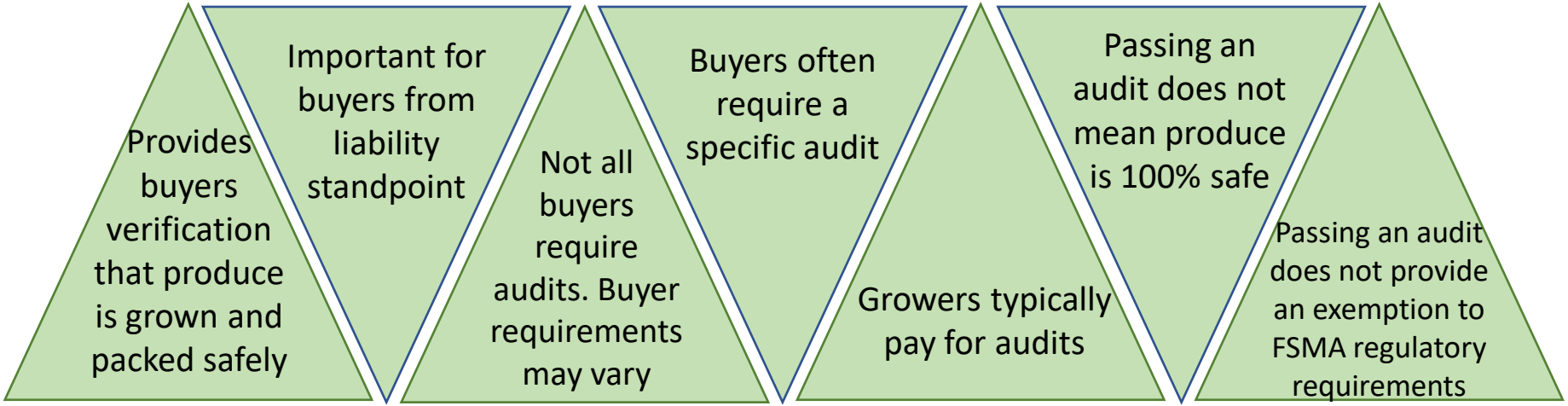


Third-Party Audits

When are audits necessary/appropriate?

- Audits are not necessary to safely grow, harvest, and pack produce
- Buyers might require it
- You might want to gain entry to a new market
- Differentiate your product(s)

Third-Party Audit Basics



Preparing for an audit

USDA GAP& GHP Audits

USDA Agricultural Marketing Service

GAP & GHP Audit

Harmonized GAP

GroupGAP

Available in Hawai‘i through North Shore Economic Vitality Partnership (NSEVP) works with farmers statewide for GroupGAP
For more info: nsevp.org

	FSMA PSR	Third-Party Audits
What Background/Structure	Required for covered farms	Voluntary, but required by buyers Nat'l or Int'l standardized audit schemes
Who Conducts/Enforces	US FDA, HDOA Inspections are not pass/fail No certificate	3rd-party agencies/companies (i.e. PrimusLabs, USDA) Pass/fail audits Certificate received for passing audit
When Frequency/Compliance	Inspections have started Once inspected successfully, less likely to be visited more than annually	Annually (announced and unannounced)
How to Prepare	Attend PSA Grower Training Complete On-Farm Readiness Review	Develop FFSP Work with audit readiness programs, extension agents

FDA FOOD SAFETY MODERNIZATION ACT

MANDATORY federal law that governs how food is grown, processed, and transported.

FSMA Produce Safety Rule

- Science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption
- Produce Safety Rule **MUST** be followed for any fruit, vegetable, or herb commonly EATEN RAW

Crops RARELY consumed raw (not covered by FSMA)

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; and water chestnuts.

- For personal, on-farm consumption
- Not a raw agricultural commodity
- Not including food grains (e.g. rice, quinoa, amaranth, oilseed)

Produce Safety Rule (PSR) Exemption for Taro

COOPERATIVE EXTENSION

Department of Agriculture
STATE OF HAWAII

For taro to be exempt from the Food Safety Modernization Act Produce Safety Rule, the taro grower must:

1. Provide documentation to the buyer that the taro "is not processed to adequately reduce the presence of microorganisms of public health significance" and
2. Obtain documentation from the buyer that they have established protocols to adequately reduce the presence of microorganisms through a validated kill step, such as heating. Refer to the Certified Federal Regulation (CFR) Section § 112.2(b)

	GROWER	CUSTOMER A [PROCESSOR]
SCENARIO 1	 Disclosure Statement to Customer A	Annual Processor Written Assurance to Grower

Sample Disclosure Statement
Taro "is not processed to adequately reduce the presence of microorganisms of public health significance"

	GROWER	DISTRIBUTOR [CUSTOMER A]	PROCESSOR [CUSTOMER B]
SCENARIO 2	Disclosure Statement to Customer A	Disclosure Statement with taro sale to Processor Sell only to customers that agree to provide Processor Written Assurance to Grower	Annual Processor Written Assurance to Distributor

Sample Processor Written Assurance
"Commercial processing follows procedures that adequately reduce the presence of microorganisms of public health significance through a validated kill step, such as heating"

	GROWER	DISTRIBUTOR [CUSTOMER A]	DISTRIBUTOR [CUSTOMER B]	PROCESSOR [CUSTOMER C]
SCENARIO 3	Disclosure Statement to Customer A	Disclosure Statement with taro sale to Processor Sell only to customers that agree to provide Processor Written Assurance to Grower	Disclosure Statement with taro sale to Processor Obtain a similar Written Assurance from processor and provide to Distributor (Customer A)	Provide annual Written Assurance to Distributor

FDA FOOD SAFETY MODERNIZATION ACT

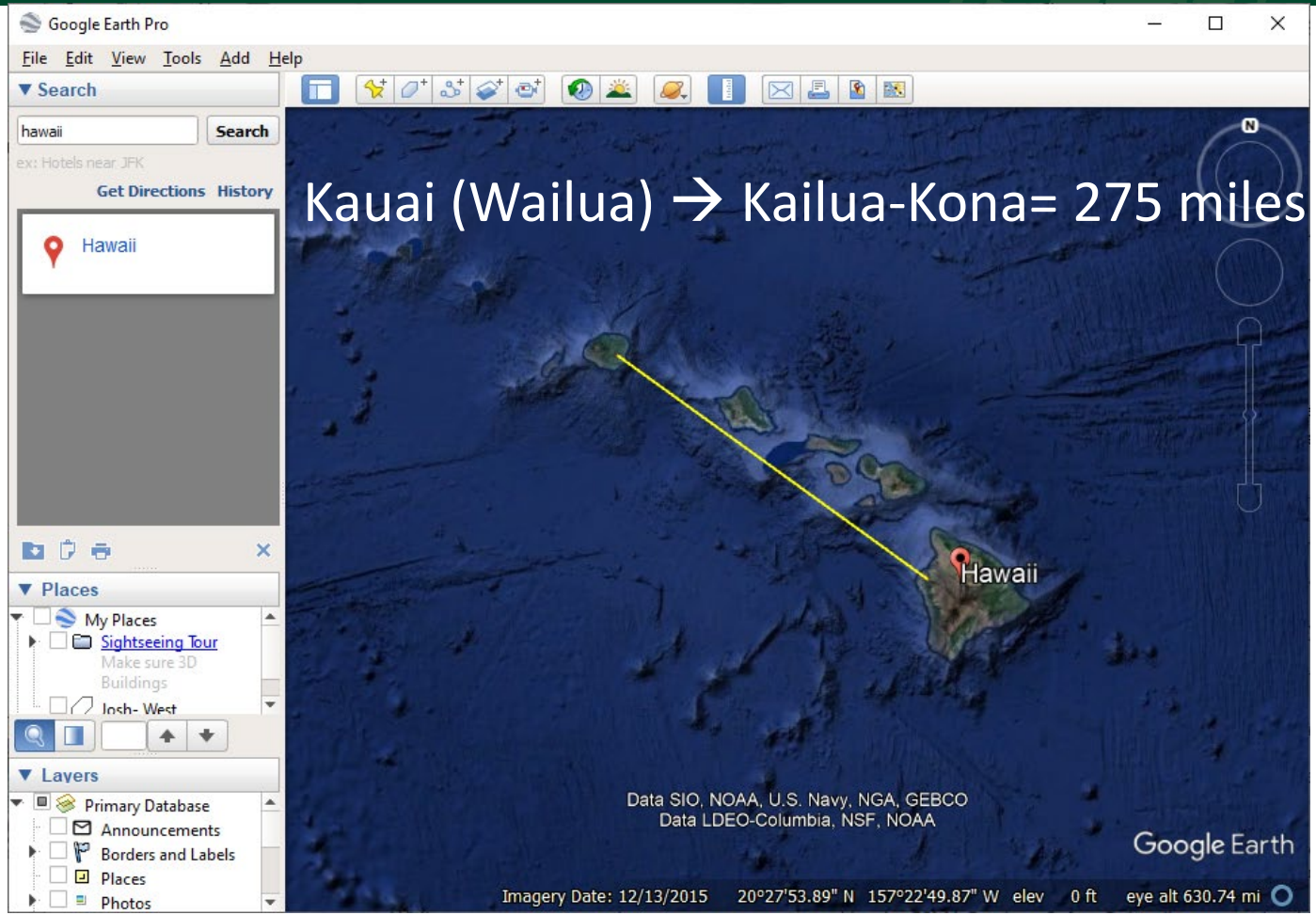
All compliance dates have passed—all farmers must comply with FSMA unless they make less than $25,000 (avg annual).

Business Size (Produce Sales Over Previous 3 Years)	Compliance Date for Most Crops	Compliance Date for Qualified Exemption	Water Related Compliance Dates
Large (> $500k)	1/26/2018	1/1/2020 For labeling	1/26/2022 (start)
Small (>$250k -$500k)	1/28/2019		1/26/2023
Very Small (>$25k-$250k)	1/27/2020		1/26/2024

Qualified Exemption

1. Average annual food sales <$500K
2. Majority of the food (by value; 51% directly sold to qualified end users
   A. Consumer of the food
   B. Restaurant or retail establishment in the same state, not >275 miles away


PC: Star Advertiser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File Edit View Tools Add Help
Search
hawaii
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ex: Hotels near JFK
Get Directions History
Hawaii
Places
My Places
Sightseeing Tour
Make sure 3D Buildings
Josh- West
Layers
Primary Database
Announcements
Borders and Labels
Places
Photos
Kauai (Wailua) → Kailua-Kona= 275 miles
N
Hawaii
Data SIO, NOAA, U.S. Navy, NGA, GEBCO
Data LDEO-Columbia, NSF, NOAA
Google Earth
Imagery Date: 12/13/2015 20°27'53.89" N 157°22'49.87" W elev 0 ft eye alt 630.74 mi

FSMA PSR Training Requirement (§ 112.22c)

At least 1 supervisor or party from farm must complete food safety training adequate by FDA

An 8-hour training,

but it's good for life!

https://www.surveymonkey.com/r/MauiPSAWaitlist

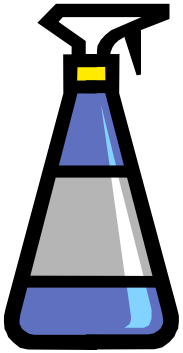
Key Requirements of FSMA and GAPs to Implement

Ways to minimize and prevent contamination of fresh produce

Food Safety Hazards

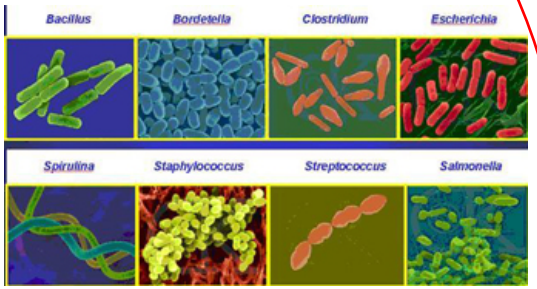
Physical

Plastic
Glass
Metal
Wood
Bandages
Jewelry



Chemical

Allergens
Pesticides
Sanitizers
Lubricants

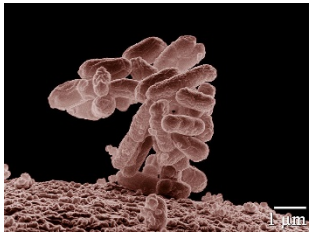


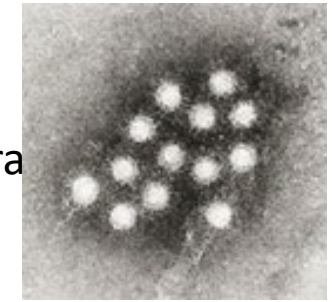
Biological

Parasites
Viruses
Bacteria

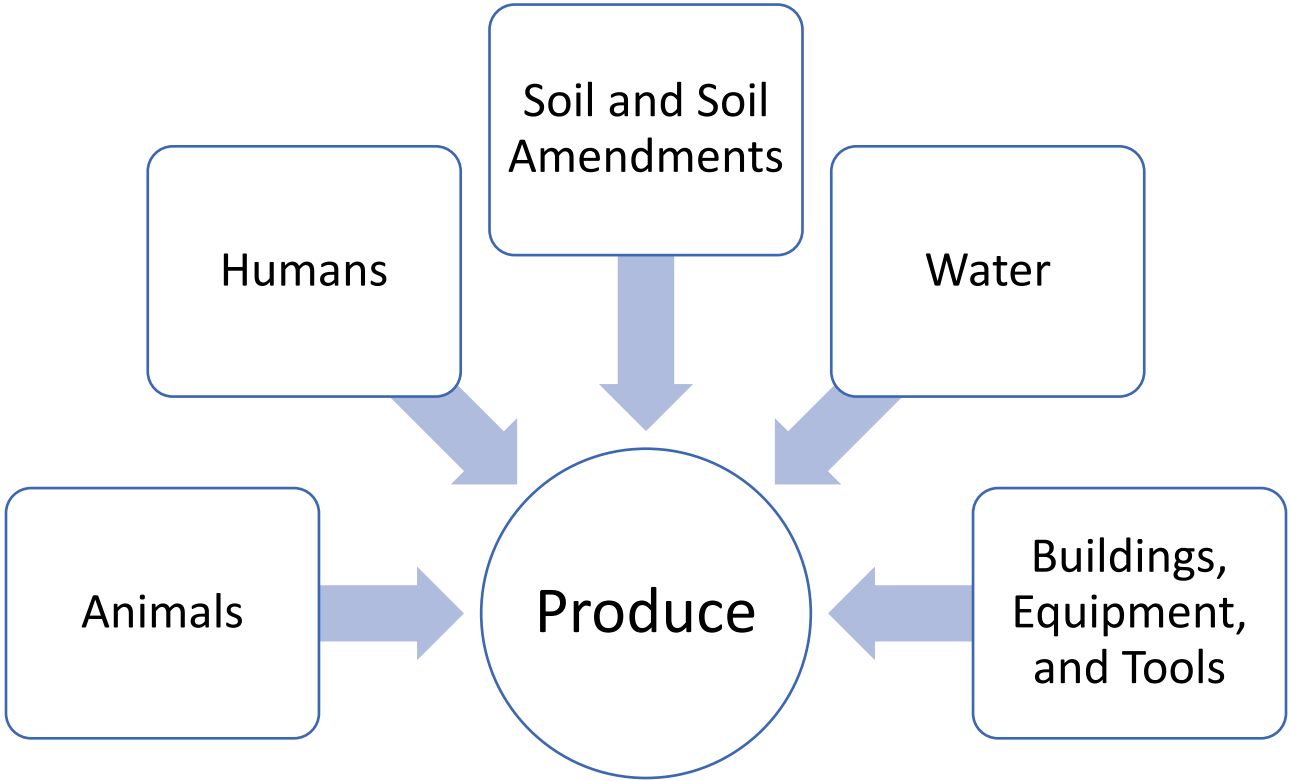
Microorganisms of Concern in Fresh Produce

- Bacteria
  - Salmonella, toxigenic E. coli, Shigella, Listeria monocytogenes
- Viruses
  - Norovirus, Hepatitis A
- Parasites
  - Giardia lamblia, Cryptosporidium parvum, Cyclospora caytenanesis, Toxoplasma gondii
  - Rat lungworm (Angiostronglyasis cantonensis)





Sources of Contamination

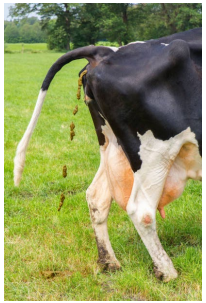


Sources of Produce Related Outbreaks

ANIMALS

E. coli O157:H7

Cryptosporidium



Salmonella

HUMANS

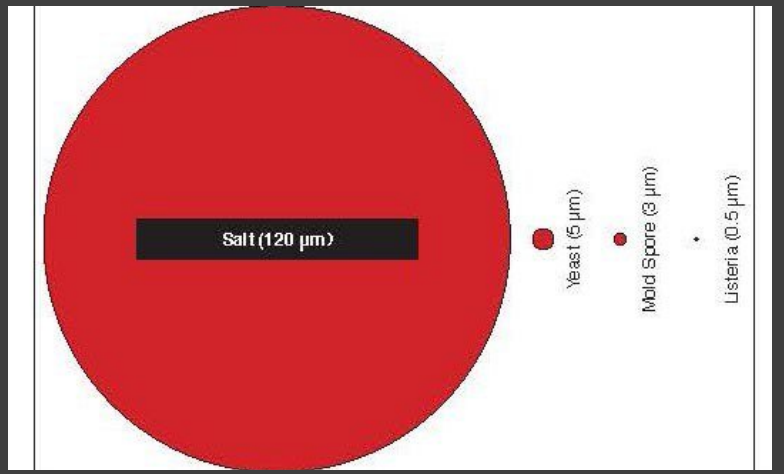
Hepatitis A

Cyclospora cayetanensis

E. coli

Challenges of Produce Safety

- Often consumed raw (no kill-step)
- Contamination sometimes cannot be detected visually—microorganisms can’t be seen easily
- Many possible sources of contamination
- Produce has texture, folds, stem areas where pathogens can harbor



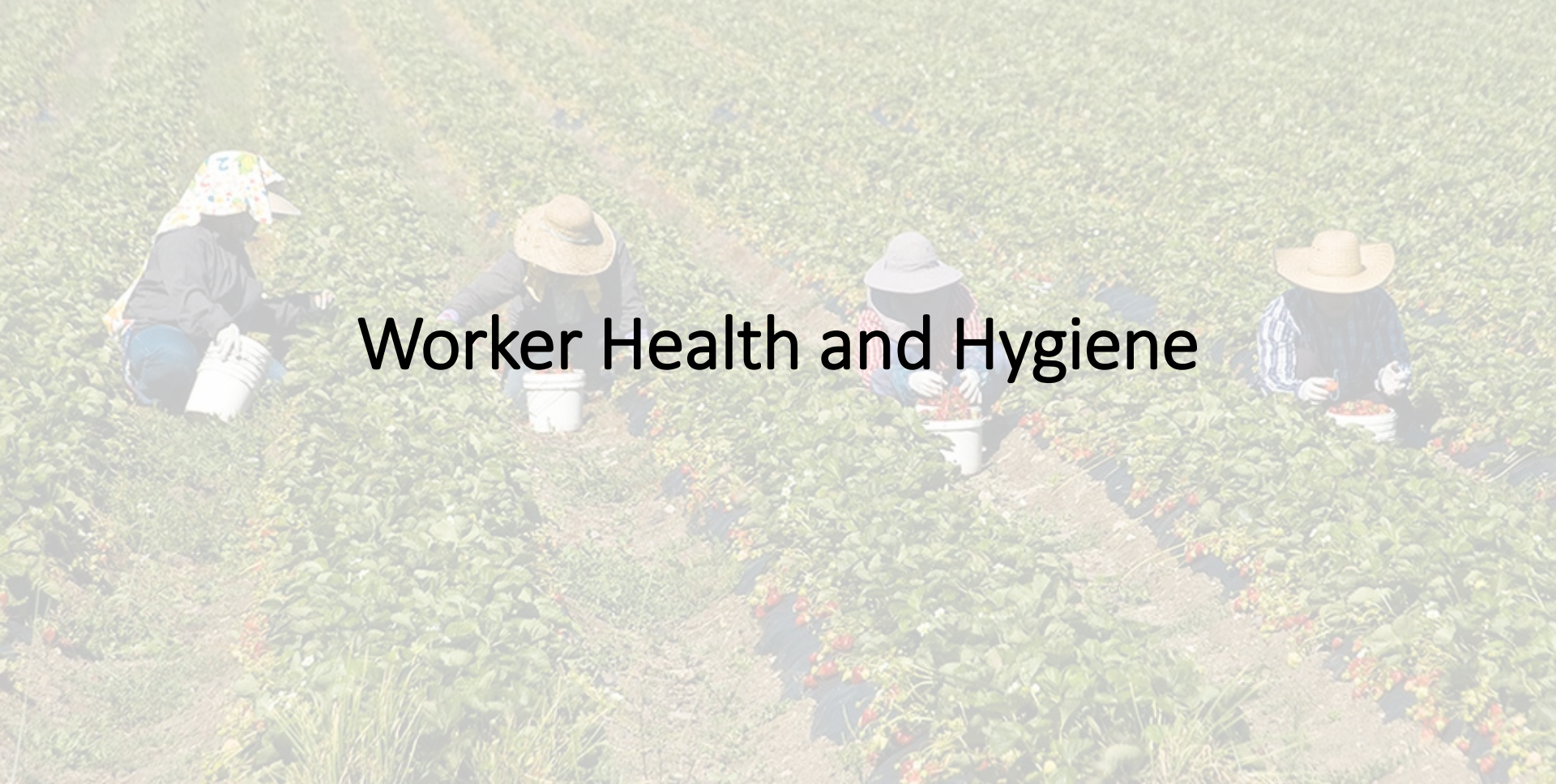
Despite these challenges…

Keeping produce safe is important because

- Farms and produce can affect many in the food system
- "Food safety begins on the farm"
- Keep your friends, family, customers, and community healthy

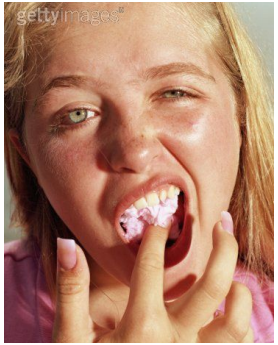
Prevention is the key to produce safety

- Farming can never be 'sterile'
- Focus on preventing contamination from occurring

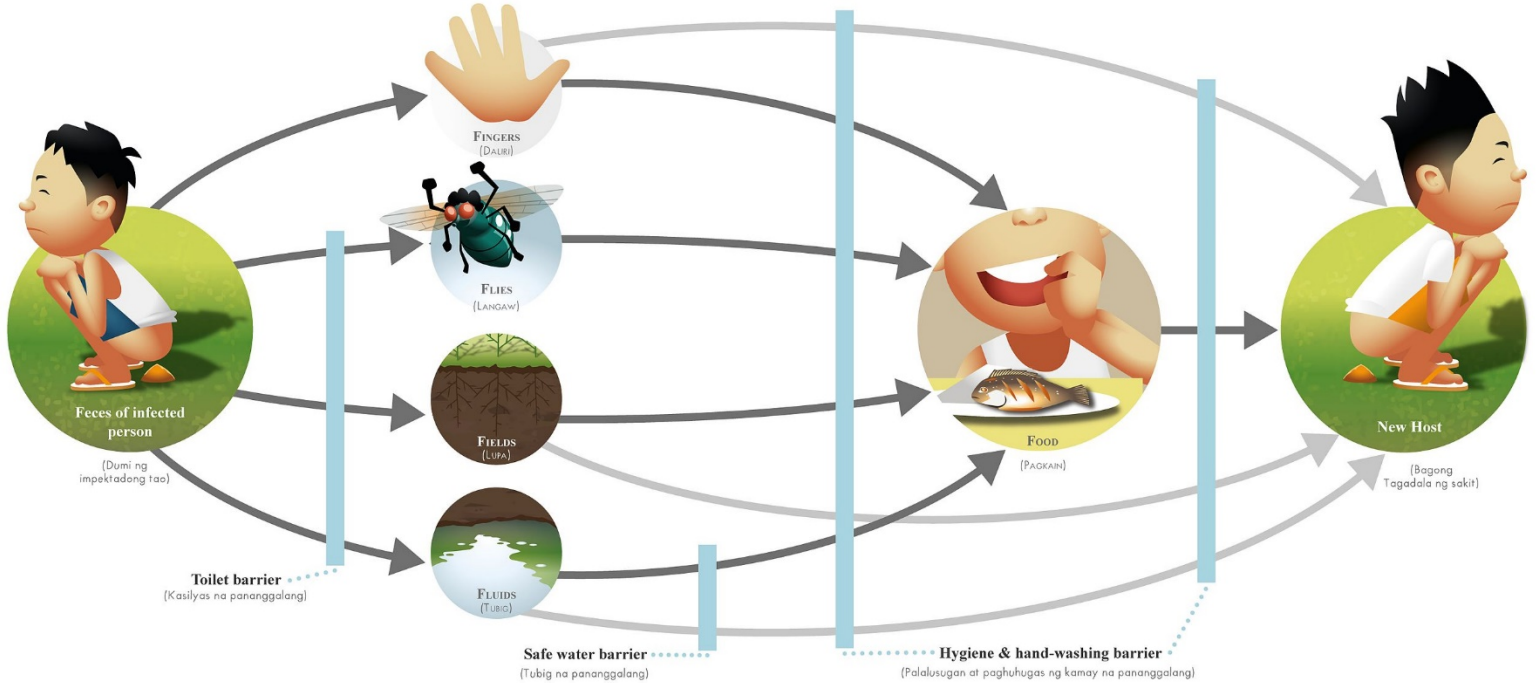


Worker Health and Hygiene

Worker Health and Hygiene



Worker Health and Hygiene



Worker Health and Hygiene

- People can carry pathogens
- People can spread pathogens
  - Harvest and packing
  - Fecal-oral route
- People need training to reduce risks
  - Handwashing
  - Illness and injuries
  - Cross contamination

Worker Health and Hygiene

- Sources of contamination- direct and indirect (cross-contamination)

Photos: Produce Safety Alliance

Worker Health and Hygiene

- **Training is key** to reducing produce safety risks (Prevention!)
- Employees must be trained at least annually
- You and your employees need to use food safety practices every day
- Anyone handling produce must be trained to identify and reduce food safety risks (volunteers, interns, friends, family)
- Visitors must be made aware of your food safety policies

Worker Training

Must be appropriate

For the duties and responsibilities

Communicate effectively

Any language barriers?

Use videos, photos, demonstrations

Teach how to identify and reduce risks!

Principles of food hygiene and food safety

Know how to recognize symptoms of foodborne illness

Examples of Training Topics:

Personal hygiene

How to evaluate contamination risks (i.e. animal activity/feces)

Harvesting: fecal contamination, dropped produce, clean harvest containers

Cleaning and sanitizing

Keep training records

Worker Health and Hygiene

- **Facilities must not be a source of contamination to produce, packing areas, food contact surfaces, and water sources**
- **Make sure facilities are easily accessible**
  - OSHA requires one facility per 20 workers within ¼ mile of the working area or a 5-minute drive
- **Keep facilities clean and well-stocked**
  - Toilet paper, soap, paper towels, etc.
- **Break areas must be designated**
  - No eating, drinking (other than water), smoking in the field

Worker Health and Hygiene

Worker Health and Hygiene

Produce handlers must:

- Maintain personal cleanliness
- Avoid contact with animals (other than working animals)
- Maintain gloves in a sanitary condition
- Remove or cover hand jewelry
- Not eat, chew gum, or use tobacco in areas used for produce handling
- Not handle produce when ill
- Wash their hands
- Never urinate or defecate anywhere except toilets

Handwashing

When

- After using the toilet
- Before starting or returning to work
- Before and after eating and smoking
- Before putting on gloves
- After touching animals or animal waste
- After working with unfinished compost
- Any other time hands may become contaminated

How

1. Wet hands with water
2. Apply soap and lather. Wash front and backs of hands and in between fingers *for at least 20 seconds*
3. Rinse hands thoroughly with clean water
4. Dry with paper towel. Turn off faucet with paper towel
5. Throw paper towel away in trash can

Hand sanitizers effective AFTER handwashing (soap=surfactant)

Worker Health and Hygiene

Gloves:

- Must be changed when they become contaminated or torn

Clothing:

- Clean clothes should be worn each day
- Separate clothing (i.e. aprons for handling animals)
- Footwear should be cleaned or designated to prevent cross-contamination

Worker Health and Hygiene

Worker injuries

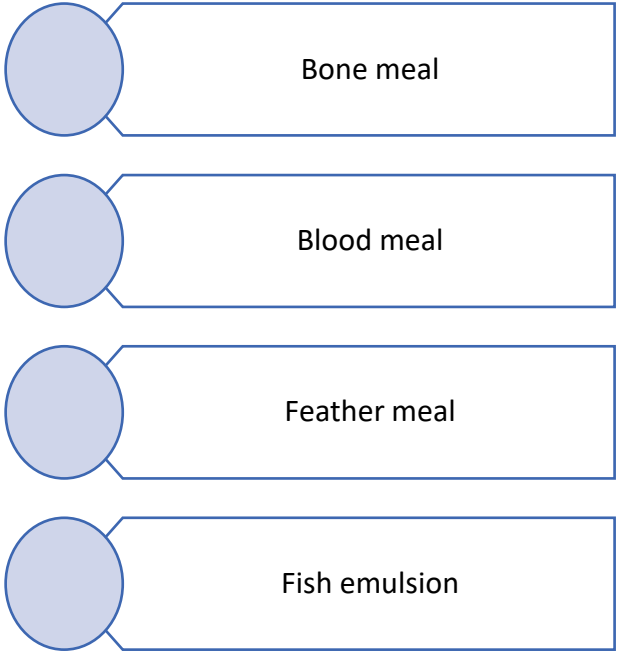
- First aid kits should be available and well-stocked
- Clean and bandage all wounds
  - A glove should be worn to create a double barrier
- Discard any produce that may be contaminated
- Clean and sanitize any items that contacted bodily fluids

Soil Amendments

Soil Amendments

Biological Soil Amendments of Animal Origin (BSAAO) are the focus of concern

- Especially untreated (raw) manure
- Amendments of animal origin should be processed to eliminate pathogens



Soil Amendments

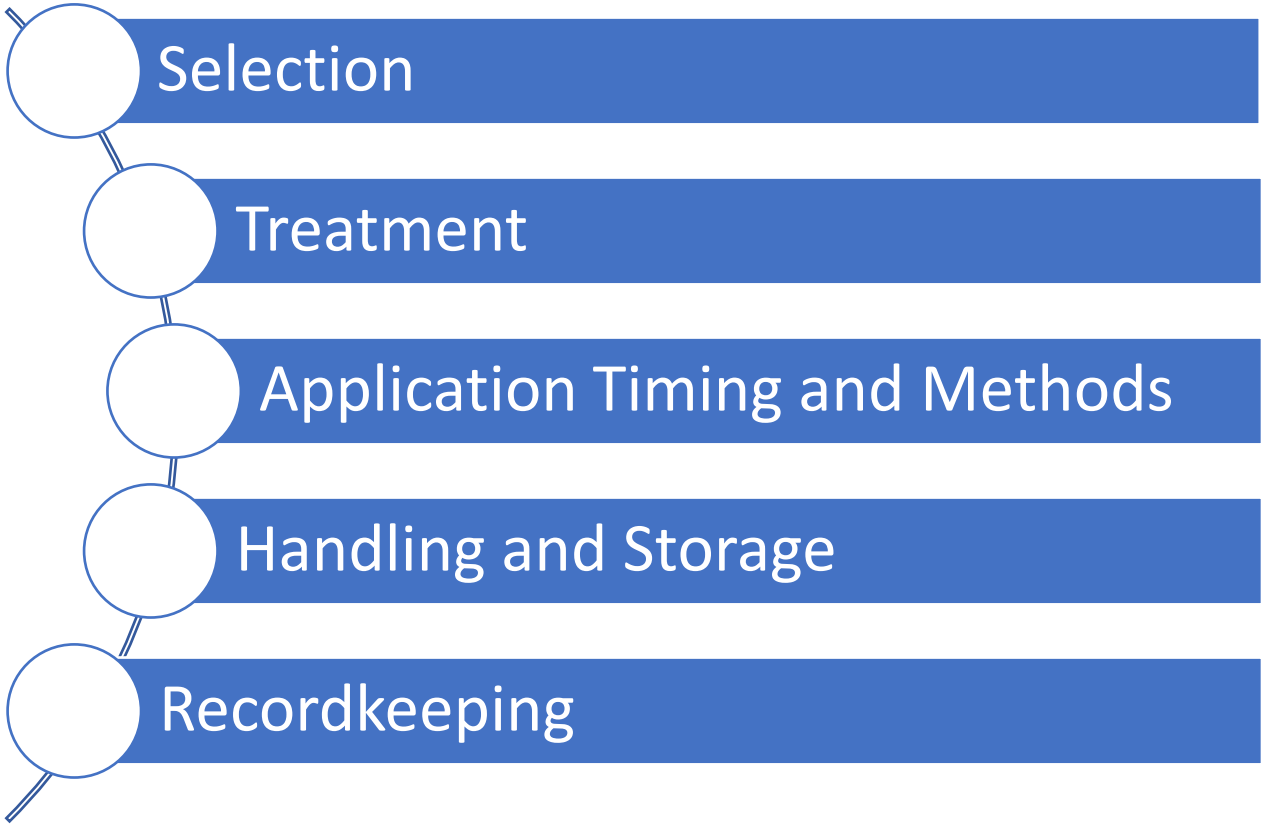
Animal Manure

- Valuable soil amendment- tilth, fertility, water holding capacity
- BUT all manures can carry **human pathogens**
- Raw manure and untreated amendments = **high risk**
  - **Have not been treated to eliminate pathogens**
  - Ex.: Raw manure, aged manure, untreated manure tea, any soil amendment mixed with raw manure

Avoid raw manure and untreated amendments

Soil Amendments

Reduce the risks of BSAAO's



Selection

Select treated amendments

Select amendments from manufacturers that have been properly treated

Treatment

Composting

- Static: 131°F (55°C) for 3 days + curing
- Turned: 131°F (55°C) for 15 days, minimum 5 turnings + curing

Application Timing

Maximize application to harvest interval

Raw manure applications (NOP regulation):

- Crops with edible portions in contact with soil: incorporate into soil at least 120 days prior to harvest
- Crops with edible portions that do not contact soil: incorporated at least 90 days prior to harvest

Application Methods

Apply soil amendments with manure to crops that are not consumed raw

Use methods to prevent contact with produce

Do not side dress with raw manure

Minimize risks to adjacent crops if spreading manure

Handling and Storage

Cover piles and build berms:

- Minimize leaching, runoff, wind drift risks
- Minimize animal access Store raw and treated compost in separate areas

Do not store close to water sources

Proper handling to prevent cross-contamination

Recordkeeping

Keep records of composting process

Keep documentation of manufacturers' treatment processes

Record applications of BSAAO's

Develop policies and procedures for sanitation

Soil Amendments- Training

Those who handle soil amendments should:

- Understand how to properly complete tasks for managing raw manure and compost
- Make sure clothes, boots, hands and/or gloves are clean before handling produce
- Wash hands before handling produce

Wildlife, Domesticated Animals & Land Use

Wildlife, Domesticated Animals & Land Use

Land Use

- Assess the field location
  - Topography, wind, water movement
  - Previous use (landfill, grazing, manure applications)
  - Impact of domesticated animals
- Assess adjacent land uses
  - Animal production, compost, manure storage
  - Residential, commercial
- Assess wildlife risks
  - Number, movement, likelihood of fecal contamination

Wildlife, Domesticated Animals & Land Use

Animals:

- Can carry human pathogens
- Can spread human pathogens by
  - Depositing feces into a field
  - Spreading fecal contamination as they move
- Are difficult to control
  - Birds and small mammals move unnoticed
  - Even fences can be breached (axis deer!)
  - Complete exclusion is not possible

Wildlife, Domesticated Animals & Land Use

Co-management

- Wildlife can be a natural and valuable part of the landscape
- Management options may be limited if animals are protected under the law
- Co-management considers both food safety and conservation of natural resources

Wildlife, Domesticated Animals & Land Use

Monitor wildlife activity while crops are growing:

- Keep animals out (as much as possible)
- Monitor for evidence of animal activity (rooting, tracks, feces, etc.)

Wildlife, Domesticated Animals & Land Use

Domesticated Animals on the Farm

- Livestock and pets may harbor human pathogens
- Don't allow animals in the field when edible portions of crops are present
- Follow policies for animal and manure handling (handwashing, tool use)
- Pets should be excluded from produce fields
- Visitors should leave pets at home

Wildlife, Domesticated Animals & Land Use

Assess fields before harvest:

- Look for fecal contamination, signs of animal activity, or other risk
- Keep records

Wildlife, Domesticated Animals & Land Use

What to do if there is contamination

- Do not harvest any produce is visibly contaminated or may contaminated
- Determine you can safely harvest the crop
- Determine if a buffer zone is sufficient to reduce risk to safely harvest of uncontaminated produce
- Handle the contamination considering risks that could result
- Document your actions

Wildlife, Domesticated Animals & Land Use

Employees training:

- Recognize evidence of animal activity
- Recognize and not harvest contaminated produce
- Wash hands after handling animal feces or any time hands may be contaminated

Agricultural Water

Agricultural Water

Production water:
Water used in contact with produce during growth

- Irrigation, fertigation, foliar sprays, pesticides, etc.

Postharvest water:
Water used during or after harvest

- Rinsing/washing cooling, ice making, handwashing, cleaning and sanitizing, etc

* All ag water must be safe and of adequate sanitary quality for its intended use!*

Agricultural Water

Source of water can influence risk of pathogens and contamination

Municipal/ County Water

Treated
(Low Risk)

Ground/ Well Water

Surface

Open to Environment
(High Risk)

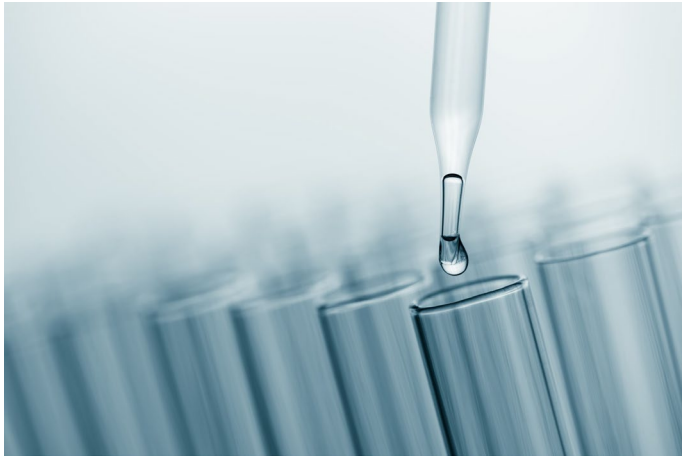
Agricultural Water

- Overhead (sprinkler)
  - Higher risk: Direct application method, contact with produce
- Flood (surface, furrow)
  - May avoid direct contact with produce
  - Risk of contact from splash
- Drip (trickle, subsurface, micro, under canopy)
  - Lower risk: Generally not in direct contact (except root crops), reduces foliar diseases, improves water use efficiency

Match irrigation method with your water quality/source and crop type!

Agricultural Water

- Water quality profiles help growers:
  - Understand the long-term quality of source water
  - Understand appropriate uses for each source
  - Determine if corrective measures are needed
- Pay attention to the water testing methods allowed by FSMA, audits



Water testing is the only way to quantitatively evaluate the microbial quality of water

Agricultural Water

For water that is used with a direct water application method under FSMA PSR:

- 126 or less CFU generic E. coli per 100 mL of water geometric mean (GM)

AND

- 410 or less CFU generic E. coli per 100 mL of water statistical threshold value (STV)

Water source	Testing requirement for FSMA PSR
Public Water Supply	Copy of test results or current certificates of compliance
Ground	Initial: 4 or more times during growing season or over the period of a year 1 or more samples rolled into profile every year after initial year
Surface	Initial: 20 or more times over a period of 2 to 4 years 5 or more samples rolled into profile every year after initial survey

Agricultural Water

What happens if production water doesn't meet the criteria?

Corrective measures

1. Apply time interval for microbial die off
   i. Between last application and harvest
   ii. Between harvest and end of storage or removal during activities such as commercial washing
2. Re-inspect the water system, identify problems, and make necessary changes and confirm effectiveness
3. Treat the water with approved methods

Agricultural Water

Agricultural Water

Postharvest Water

- Not all risks can be eliminated in the field
- Postharvest water has the potential to spread contamination widely (cross contamination)

Agricultural Water

Sanitizers in postharvest water:

- NOT intended to "wash" produce, but instead to prevent cross-contamination
- Must be labeled for intended use (Ex. In water or for contact with fruits and vegetables

Always read and follow the label on sanitizers

Agricultural Water

Postharvest Water Quality:

Must have zero detectable generic E. coli per 100 mL of water (FSMA PSR)

- Direct contact with produce during or after harvest
- Direct contact with food contact surfaces
- To make ice
- For handwashing

Untreated surface water cannot be used for these purposes

Agricultural Water

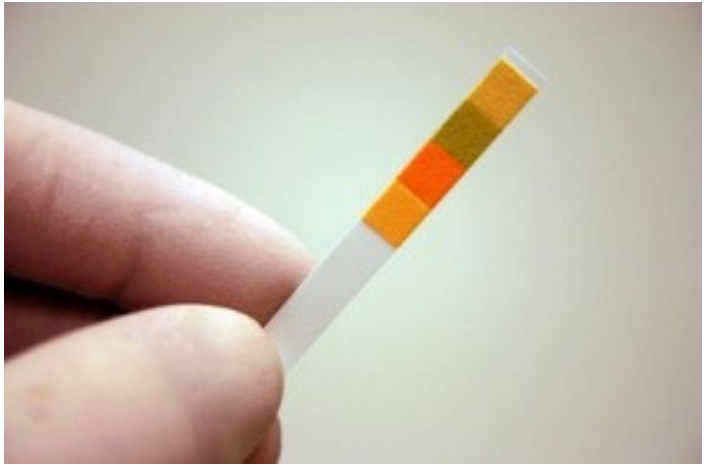
Source	Testing Requirements
Untreated Ground Water	4 or more times during the growing season or over the period of a year 1 or more tests per year after initial year
Public Water Supply	Copy of test results or current certificates of compliance

Agricultural Water

When to change wash water

Consider:

- Organic load (soil, leaves, decayed/damaged product)
- Turbidity
- Volume of produce
- Type of produce
- Type of antimicrobial product



Agricultural Water

Disposing of Used Water

- Must be disposed of properly so that become a source of contamination to fields and harvested produce
- Handwashing stations need catch basins if not connected to a drain

Harvest, Postharvest Handling & Sanitation

Harvest Sanitation

- Start with clean and sanitized harvest bins, baskets, and tools
- Keep harvest bins off the ground, or use a barrier
- Never harvest produce with fecal contamination
- Do not harvest dropped produce

Postharvest Handling & Sanitation

Think about everything that touches or impacts produce:

- Harvest and packing containers
- Harvesting tools
- Packing equipment
- Hands and clothing
- Postharvest water
- Buildings (coolers and storage areas)
- Transport vehicles

Keep things clean during harvest and postharvest handling!

Postharvest Handling & Sanitation

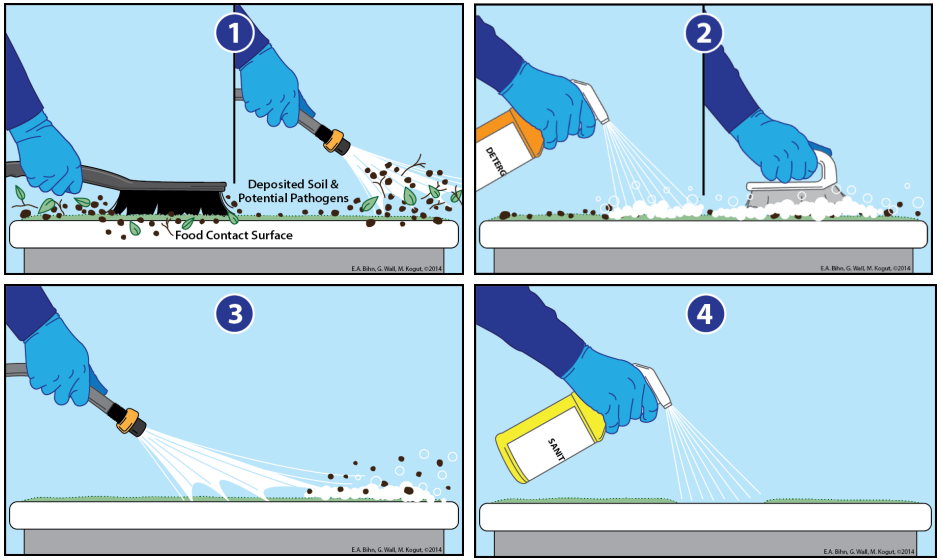
Packinghouse Sanitation Basics

- Good housekeeping--keep it clean and organized!
- Provide hygiene facilities and training so that practices are properly implemented
- Keep produce and packing containers off the ground and covered
- Eliminate and manage pests and debris
- Minimize standing water
- Proper cleaning and sanitizing
  - Focus initial efforts on direct food contact surfaces (hands, bins, tables, racks, tools/utensils, etc.)

Postharvest Handling & Sanitation

Cleaning vs. Sanitizing

- **Cleaning:** Physical removal of dirt (soil) from surfaces which can include the use of clean water and detergent
- **Sanitizing:** Treatment of a cleaned surface to reduce or eliminate microorganisms



You can't sanitize a dirty surface. Cleaning always comes first!

Postharvest Handling & Sanitation

Packing Containers

- Should be new, single-use OR reusable containers that have been cleaned
- Packing containers and materials should be stored in a covered area and kept off the floor

Postharvest Handling & Sanitation

Excluding and Minimizing Pests

- Inspect all walls, doors, windows
  - Repair holes and cracks
  - Make sure door seals are in place to prevent pest entry
- Use bird deterrents such as nets or spikes
- Keep doors and windows closed as much as possible
- Cut grass around the packing area
- Remove culls and garbage daily and as needed throughout the day
- Keep produce covered

Postharvest Handling & Sanitation

Transportation

- Multipurpose vehicles or personal vehicles
  - Must be cleaned before use with produce
  - Can use a clean liner as a barrier if adequate to prevent contamination
- All vehicles should be cleaned and inspected before use with produce
  - Clean, free from physical debris and off odors
  - Check refrigerated vehicles to make sure units are working properly and at adequate temperature

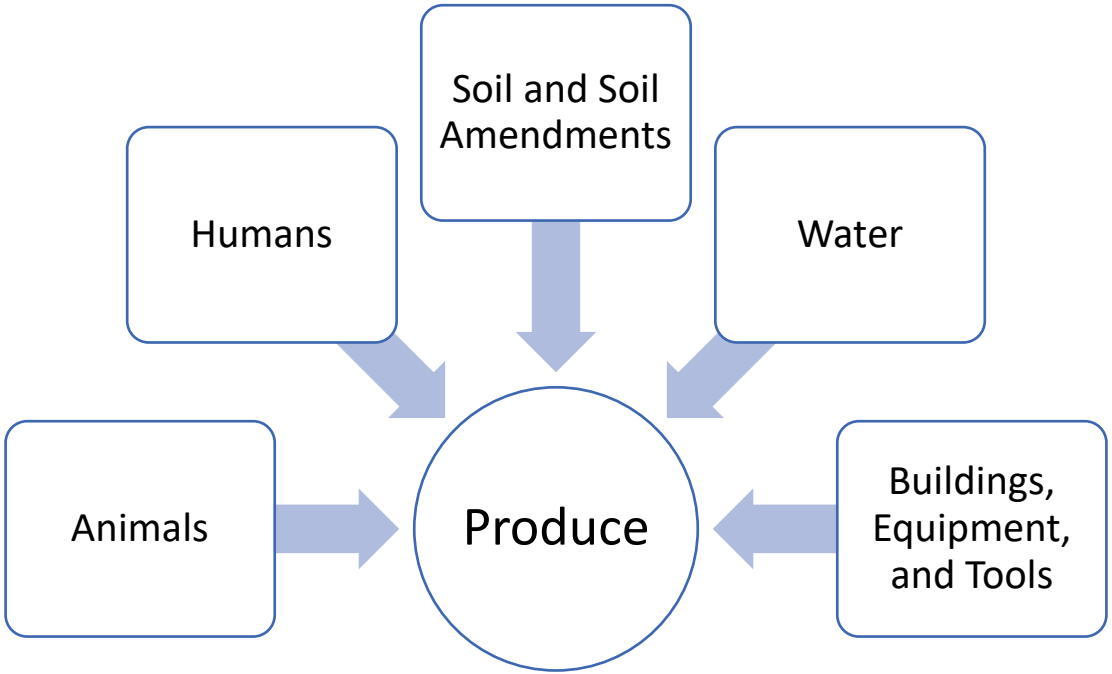
Traceability

Traceability

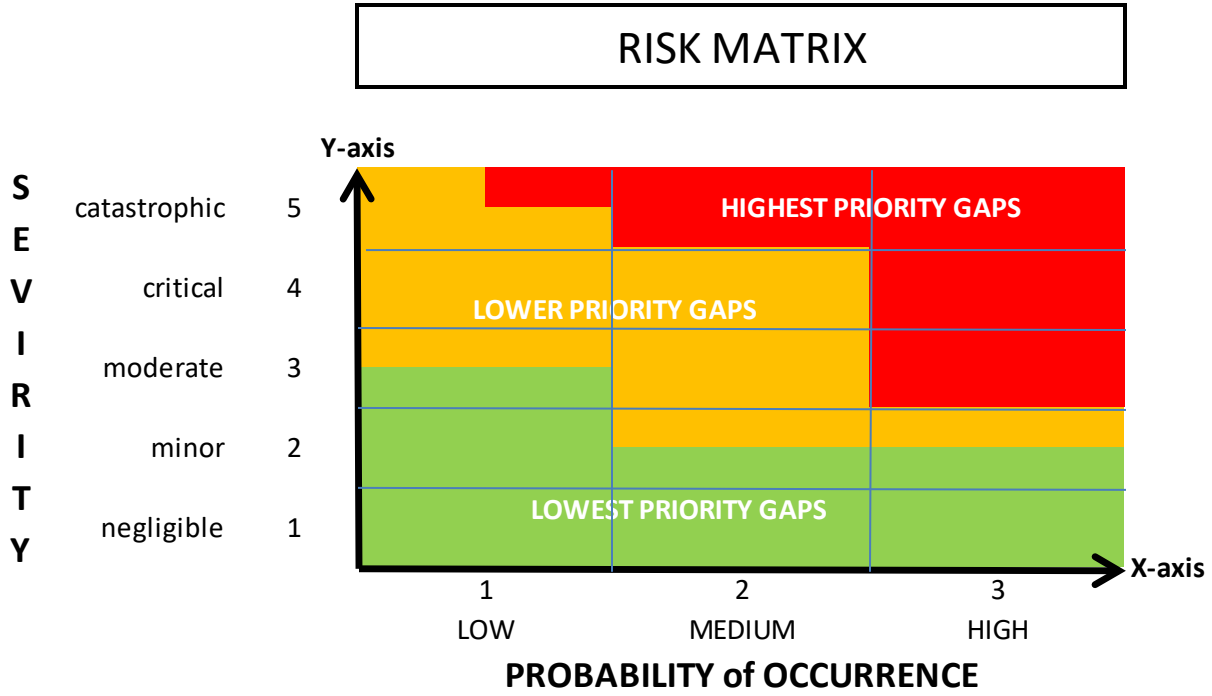
- Be able to track your product one step forward (to buyer), and one step back (to field)
- Establish lots or segments
  - Easier to identify if you need to recall
  - Prevents the need to recall everything
- Keep track of what was harvested, when it was harvested and the fields it came from
- Each item should be labeled with farm address, phone number, email address

Summary

Sources of Contamination



Risk Assessment and Risk Management



Risk Assessment and Risk Management

1. Assess Produce Safety Risks
2. Implement Practices
3. Monitor Practices
4. Use Corrective Actions
5. Keep Records

Produce Safety Alliance Grower Training

Remote delivery until further notice (via Zoom)

Join the Maui/Lana'i Waitlist:
https://www.surveymonkey.com/r/MauiPSAWaitlist

www.manoa.hawaii.edu/ctahr/farmfoodsafety

www.producesafetyalliance.cornell.edu

Questions?

Thank you!

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