

Food Safety Modernization Act and Good Agricultural Practices An Update for Produce Growers

Marlin A. Bates
Horticulture Agent
K-State Research and Extension
Douglas County

Farmers and Food Safety

- FSA Produce Safety Rule
 - Exemptions
 - Qualified Exemptions
 - May be revoked
 - May be reinstated
- GAPs Certification
 - Food Safety Plan
 - 3rd Party Audit
- Good Agricultural Practices
 - Every Producer's Responsibility

Five Main Parts of FDA Food Safety Modernization Act

Act signed in Jan 2011- response to food borne illnesses

- 1. Produce Safety Rule – *Final rules: Nov 13, 2015***
- 2. Preventive Controls for Human Food – *Final rule published Sept 10, 2015***
- 3. Preventive Controls for Animal Food- *Sept 2015***
- 4. Foreign Supplier Verification Program**
- 5. Accredited Third Party Certification**

Food Safety Modernization Act- Produce Safety Rule

- Final rule released in November 2015
- Focus on growing, harvesting, packing, holding produce
- First ever government regulation for the production, harvest, and handling of fruits and vegetables
- Similar requirements to USDA GAPs (buyer requirement)



Produce Safety Comment Periods

- First comment period closed November 2013
- Over 15,000 comments received
- Key provisions reopened for comment on September 29, 2014, including:
 - Water quality standards
 - Raw manure and compost
 - Mixed use facilities
 - Procedures for withdrawing the qualified exemption for certain farms
- Final comment period closed Dec. 15, 2014

Produce Safety Rule - Exemptions

- The Rule Does Not Apply To:
 - Produce that is not a raw agricultural commodity
 - Produce commodities that the FDA has identified as rarely consumed raw
 - Food grains
 - Produce for personal or on-farm consumption
 - Farms that have an average annual value of produce sold during the previous three-year period of \$25,000 or less.

Produce Safety Rule – Qualified Exemptions

- Sell \leq \$25,000/ year in produce sales (on average over previous 3 years) **EXEMPT**
- Produce is rarely consumed raw (pumpkin) **EXEMPT**
- On average (over past 3 years), have
 - $<$ \$500,000 annual food sales AND
 - Majority of food sold directly to “qualified end user”
 - **EXEMPT, but** have some record-keeping requirements

What does FSMA cover?

- Similar to GAPS- Good Agricultural Practices
 - Agricultural water (irrigation, wash)
 - Biological soil amendments (manure, compost)
 - Domesticated and wild animals
 - Personnel qualifications, training, and health and hygiene
 - Equipment, tools, buildings, & sanitation



Produce Safety training requirements

- EVERYONE covered by FSMA will need to go to certified training (1 day)
 - Regardless if you are GAP certified, have been to other training, have other certifications, etc.
 - KSU and MU Extension plans to start offering these courses in 2016/ 2017
 - We are working to get grant funding to subsidize producer trainings



FSMA Key points

- GAPs will be updated to ~match FSMA
- If you pass a GAPs audit, ~FSMA compliant (but still need FSMA training)
- On-farm food safety plan, audit NOT in FSMA
- Info on enforcement of FSMA forthcoming

FSMA Key points-2

- Raw manure application – harvest interval to be further studied
- No detectable E.coli in water directly contacting produce after harvest
- FDA aware of need to protect endangered wildlife species (not destroying their habitat)



Food Safety On the Farm

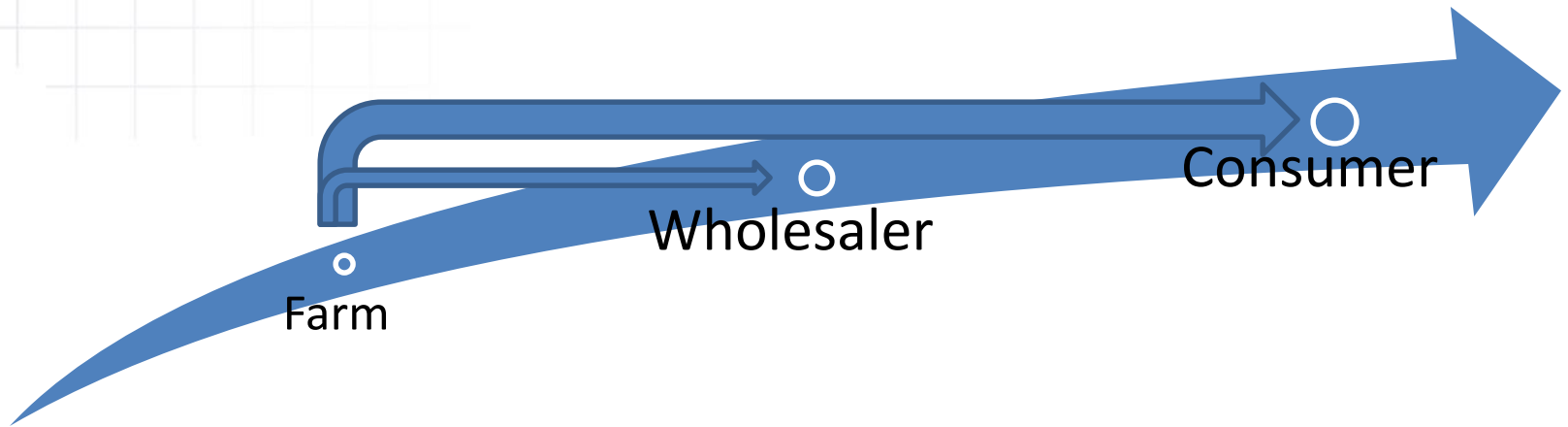
An Introduction to: Good Agricultural Practices

What is GAPs?

- Administered by USDA-Agricultural Marketing Service Program
- A Voluntary Third-Party Audit Verification Program
 - This third-party is typically the USDA-AMS, but some state agencies conduct audits
- Based on the FDA's "[Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables](#)"

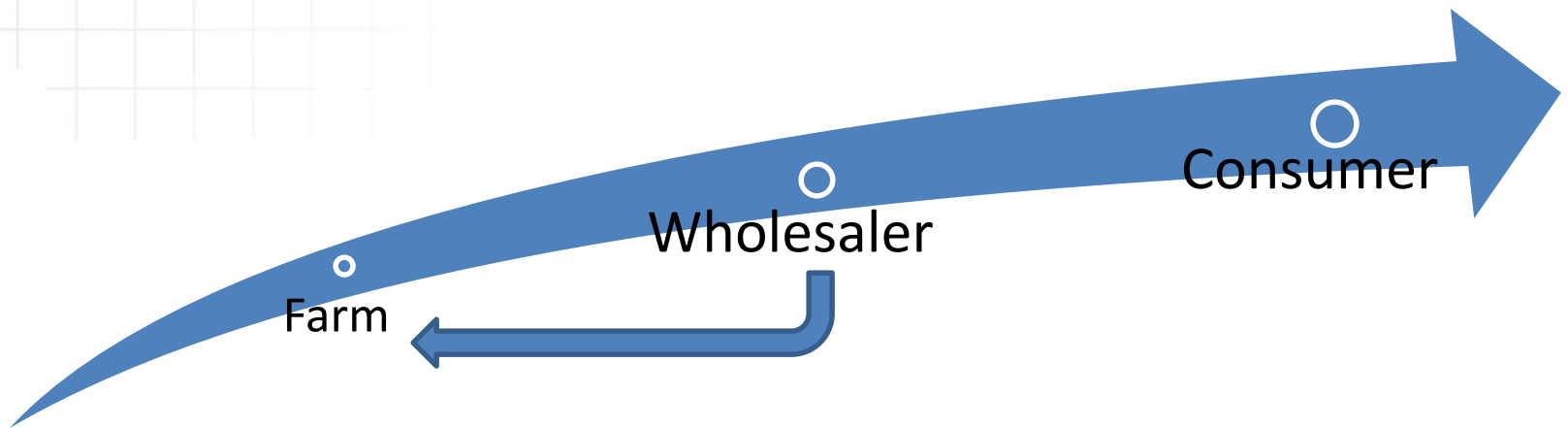
GAPs Certification is...

- ...a quality assurance tool that works in all directions
 - A way for farms to communicate the safety of their product to their buyers



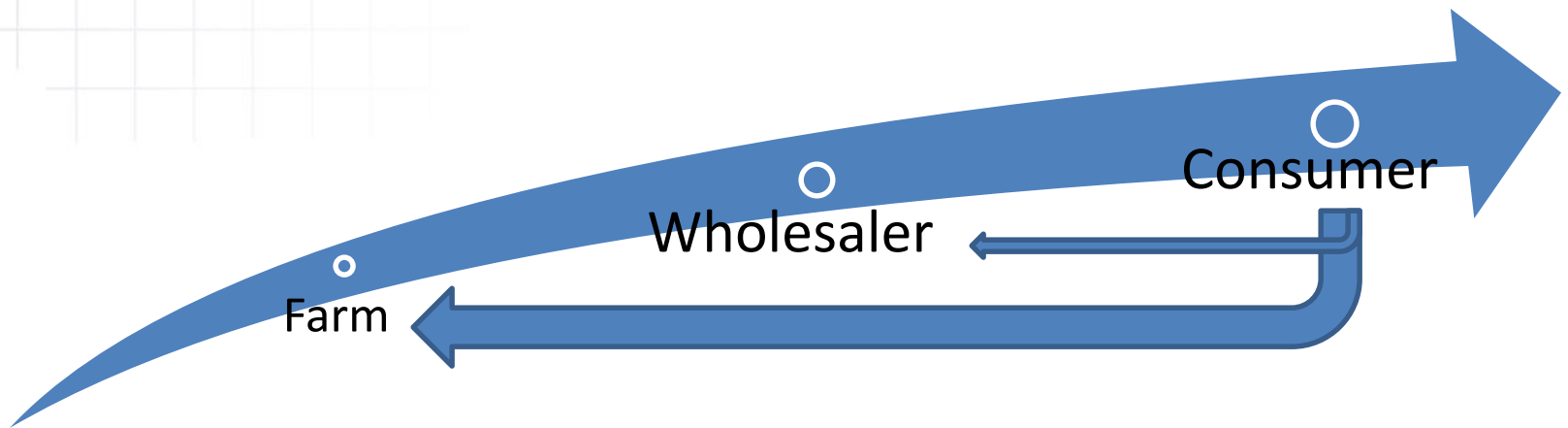
GAPs Certification is...

- ...a quality assurance tool that works in all directions
 - A way for distributors to know that the farms they are buying from are reducing contamination risks



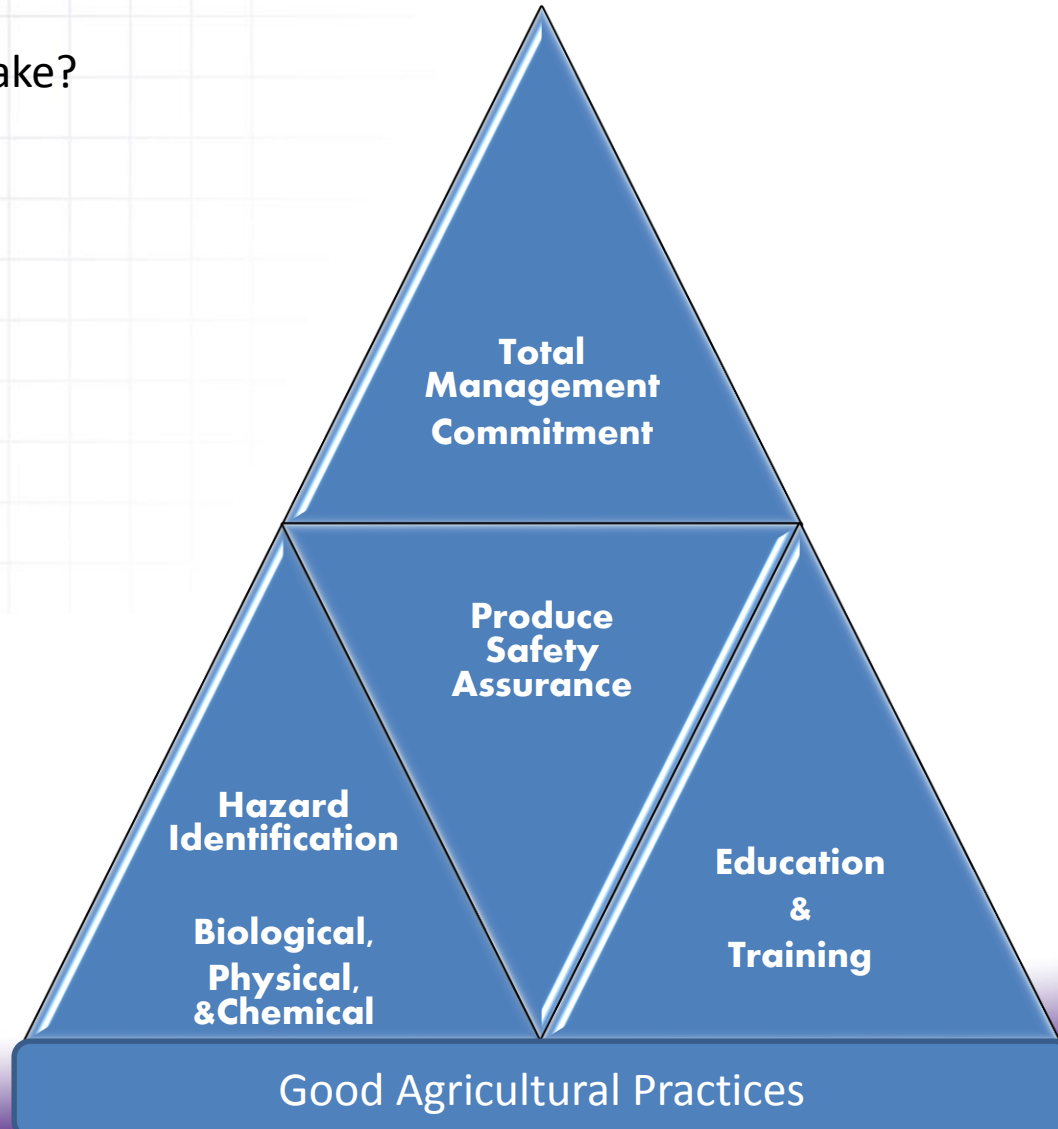
GAPs Certification is...

- ...a quality assurance tool that works in all directions
 - A way for consumers to know that the food they're buying is protected from contamination

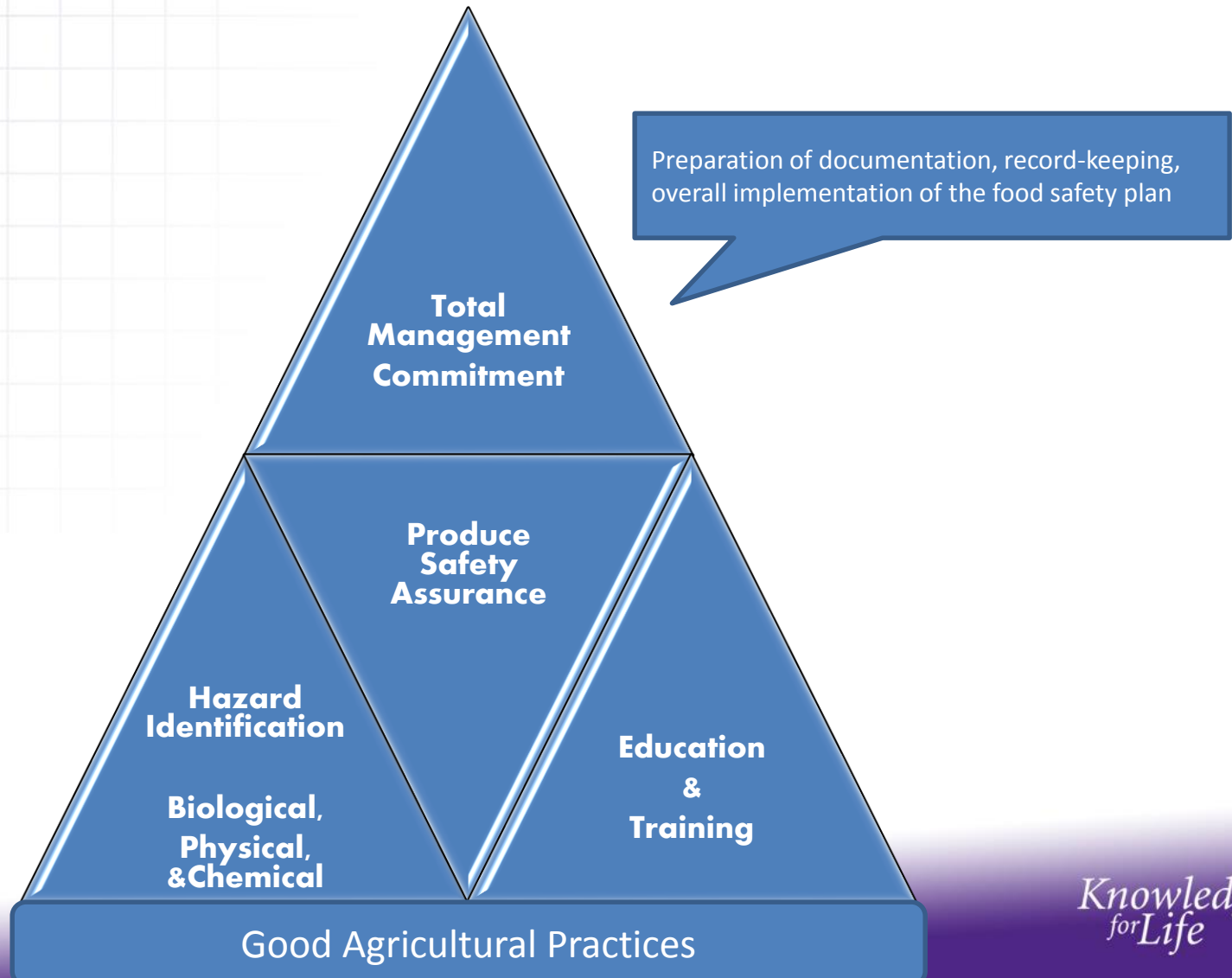


Implementing a Food Safety Plan

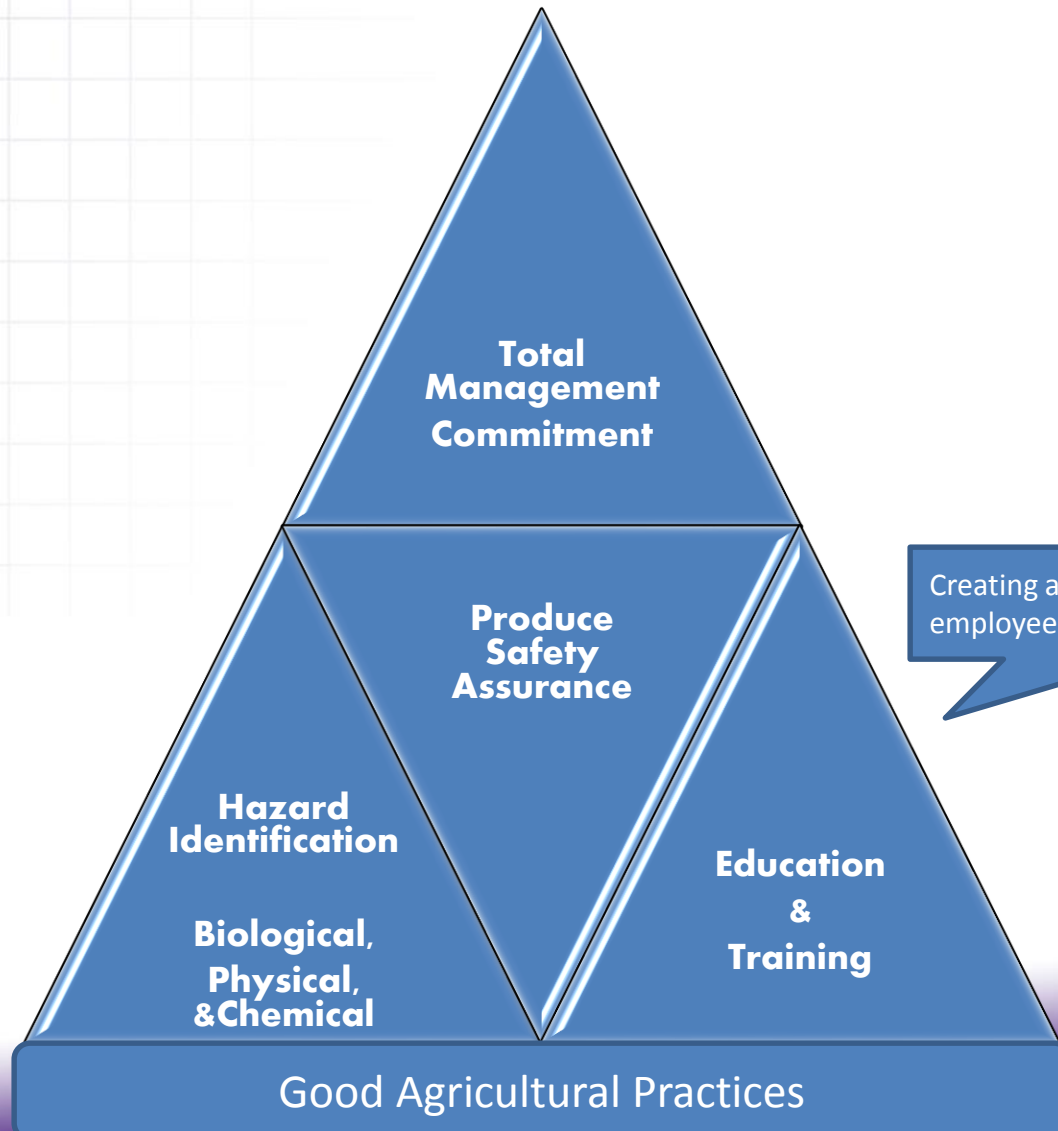
What does it take?



Implementing a Food Safety Plan

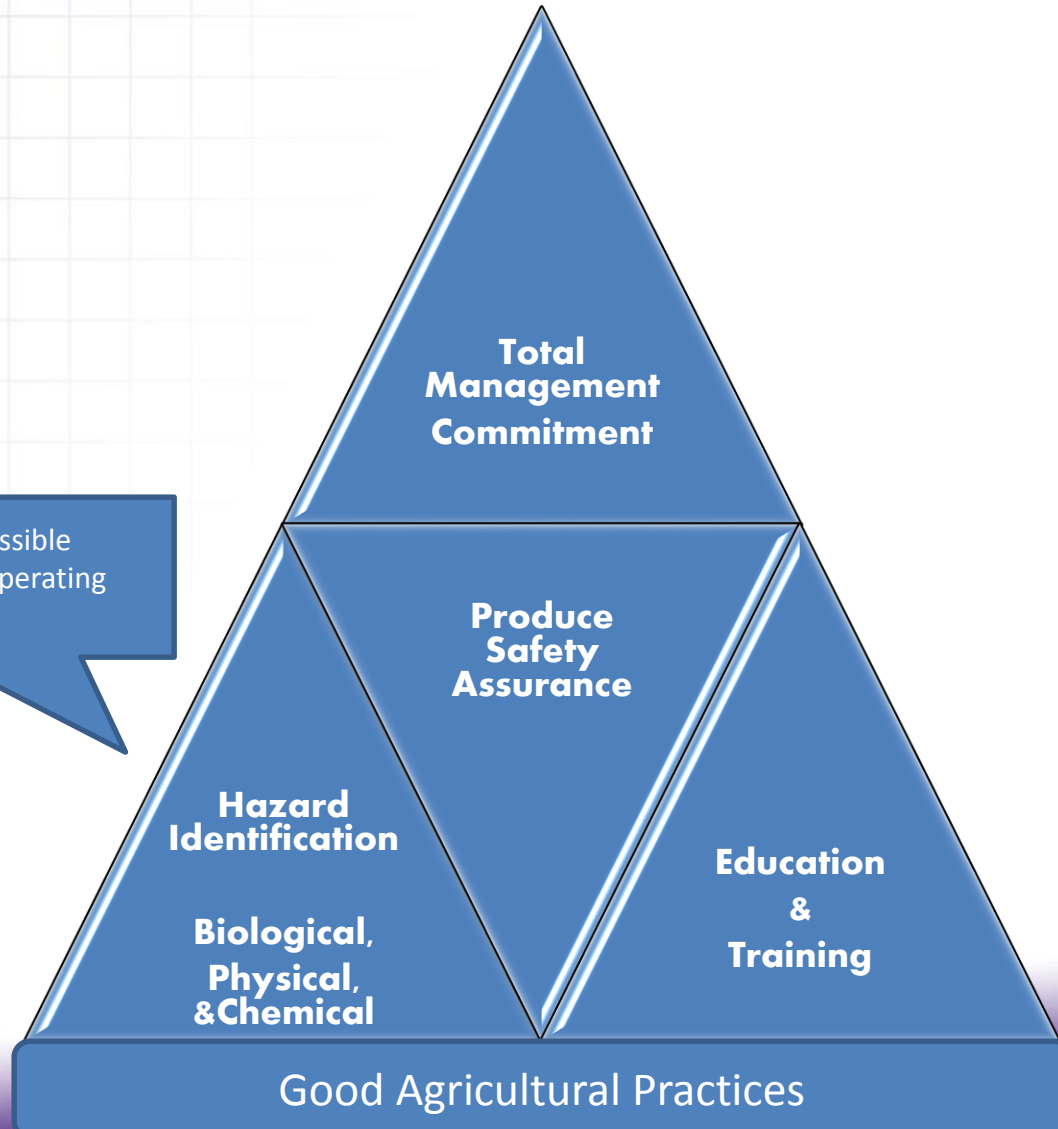


Implementing a Food Safety Plan



Creating awareness and “buy-in” from employees and visitors

Implementing a Food Safety Plan



Develop an awareness of possible threats and put “Standard Operating Procedures” in place.

Who Needs GAP Certification?

- Producers who's markets require food safety certification
- Producers who anticipate that their markets will soon require it



Steps in Becoming Certified

- Develop a farm food safety plan
 - There are resources to assist with this
- Name an individual to implement the plan
- Develop a notebook with documents necessary to log required activities
- Work through the USDA-AMS Audit Verification Checklist to make sure that you're addressing all needs

USDA-AMS Audit Checklists

- [USDA-AMS Fresh Products Food Safety Homepage](#)
- Harmonized Audit Protocols:
 - [Field Operations and Harvesting Standard](#)
 - [Postharvest Operations Standard](#)

Who Doesn't Need Certification

- If your buyer doesn't require, you don't need a food safety certification.
- **HOWEVER**, it is considered every producer's responsibility to ensure a safe food supply
 - This means following guidelines set forth as Good Agriculture Practices regardless of intent to certify.

GAPs Focus Areas

- Worker Hygiene and Health
- Water and Flooding
- Soil, Manure, and Compost
- Harvest/Post-Harvest

Worker Health and Hygiene

When To Wash Your Hands

- After using toilet
- After cleaning restroom
- After smoking, eating or drinking
- After changing diapers or linens
- After handling garbage
- After caring for or touching animals
- After handling dirty equipment, utensils or farm machinery
- Before you eat
- Before you start to work
- Before handling food
- Between changing tasks or changing gloves
- After engaging in other activities that soil hands

Do You REALLY Know How to Wash Your Hands?

- 1. Wet hands with warm water
- 2. Apply soap to hands
- 3. Lather hands briskly for 20 sec. Areas of concentration:
 - Palm to palm
 - Palm on backs of hands
 - Claw paws in palms
 - Between fingers
 - Scrub forearm near wrists.
 - Left and right hands
- 4. Rinse thoroughly
- 5. Towel dry thoroughly with disposable paper towel

Note: Lathering for less than 20 seconds is not good enough!



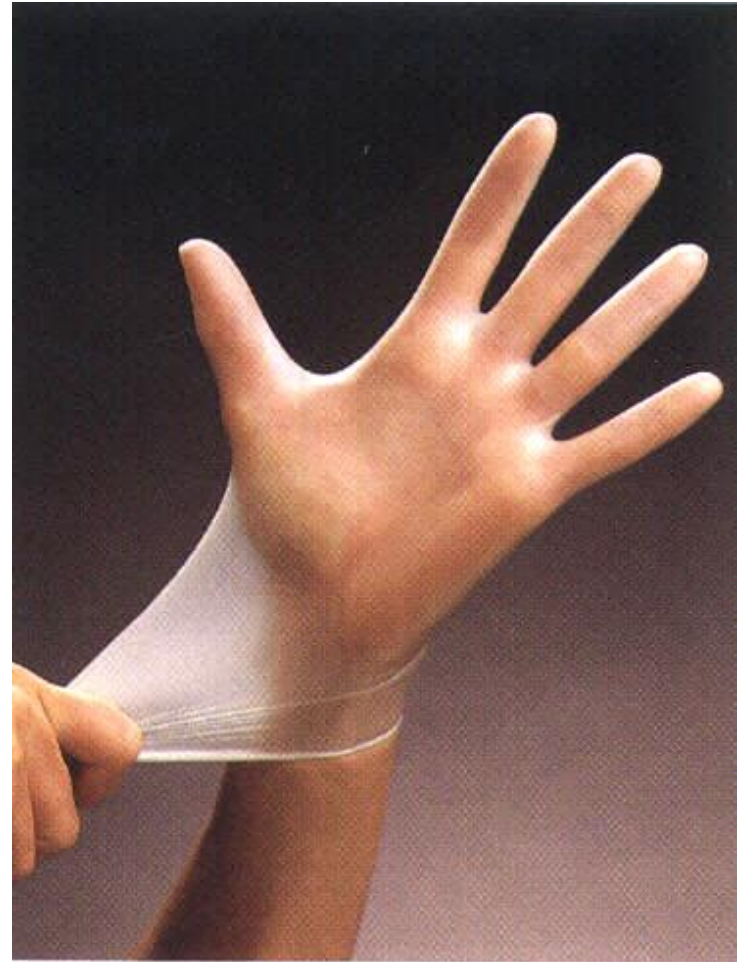
Using Hand Sanitizers

- Is not a substitute for hand washing
- Hands must be clean before sanitizer is used
- “Experts” recommend using only alcohol-based sanitizers with emollients to prevent drying & chapping of skin
- Use before bare-hand contact with ready-to-eat (RTE) foods



Use of Gloves

- Hands must be **washed** before being gloved
- Hands must be dry before putting on gloves
- Use gloves for only one task
- Caution on use of latex gloves...
 - They can cause allergies in both you and in consumers
- Wash your hands after removing gloves



Sick Employees & Field Workers

- Sick workers (including yourself or your children) should not work with produce.
- Establish and communicate a clear policy that allows workers who report illness (vomiting, diarrhea, etc.) to be assigned to paid activities that do not bring them into contact with food or food equipment/utensils



Do Not Work If Ill



Copyright © International Association for Food Protection

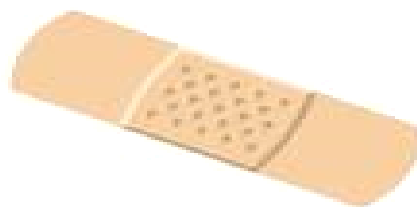
Employee Health & Hygiene: Cuts

- When Somebody Cuts Their Finger While Harvesting and it Bleeds, What Should You Do?

- Remove Worker From Harvest Area to Treat and Cover Wound
- Wound Should be Bandaged & Gloved Before Continuing Work
- Border Off Area & Don't Harvest Contaminated Product

Worker Hygiene: Wounds & Bandages

- Maintain adequate supply of bandages
- Arms, wrists, or forearms that have an infected wound should be covered with a dry, tight fitting, waterproof bandage and an outer covering for the entire bandage
- A wound that contains pus and is located on a part of the body that could contact produce, processing equipment or tools presents a contamination risk.
- A worker with a wound that cannot be adequately covered to prevent contact with produce, processing equipment, or tools should not work with produce, processing equipment or tools until the wound has healed.



Toilet & Hand Washing

- Individuals relieving themselves in the field presents a substantial risk of contamination.
- Have handwash facilities available at all times.
- Ensure that all employees are trained in hand washing and proper use of gloves
- Establish frequency of toilet and hand wash facility maintenance/sanitation (cleanliness, soap, towels, toilet tissue, waste cans)



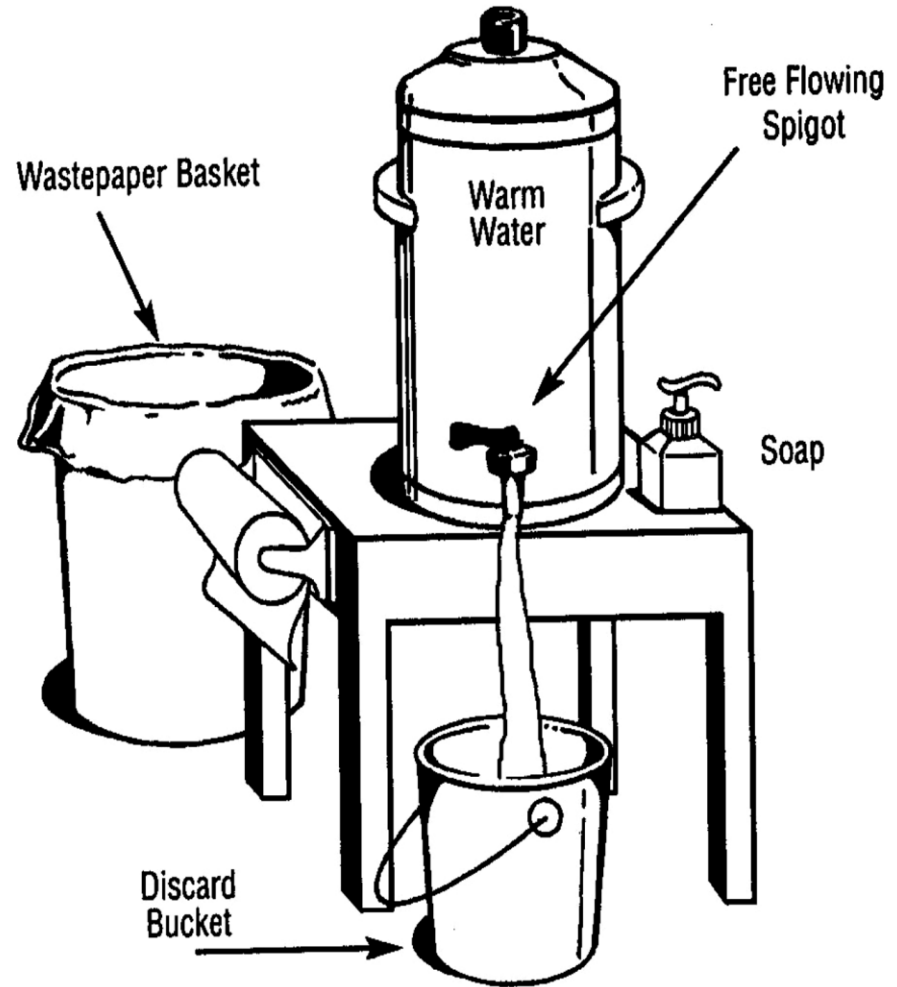
Hand Harvest

- Adequate # of approved hand wash stations should be available
- General Rule—1 hand wash station for every 20 employees
- Minimum of 15 gallon water storage capacity recommended for hand wash stations



The Hand Washing Facility

- The hand washing facility must be accessible at all times
- Do not block hand washing facility for any reason:
 - Equipment storage
 - Farm or Harvest
 - Tables and carts, etc.
- Have plenty of reserve, potable water on hand or refill containers routinely
- Remember: Use of hand sanitizers is not hand washing!



Portable Toilets

- Should be provided if restroom is not easily accessible
- Adequate # of field latrines should be provided, strategically located, and serviced routinely
- General rule of thumb—1 toilet for every 20 workers
- Use caution when servicing portable toilets to prevent leakage into the field



Field Toilet or Restroom Placement

- Should be easily accessible to employees
- No more than $\frac{1}{4}$ mile away from workers
- Think about installing toilets on trailer for mobility within the field
- Remove units from field for sewage collection and servicing
- DO NOT locate near irrigation water sources

Employees need to be able to use toilet facilities whenever they need... This decreases the likelihood of employees relieving themselves in the field and causing contamination of food products

GAPs Focus Areas

- ~~Worker Hygiene and Health~~
- Water and Flooding
- Soil, Manure, and Compost
- Harvest/Post-Harvest

Water and Flooding

Sources of Contamination

#1= Water

Anytime water comes in contact with fresh produce, the water's quality determines the potential for pathogen contamination, since water may be a carrier of a number of types of microorganisms.

Agricultural Water

- Usually, water for agricultural uses comes from:
 - Surface sources such as rivers, streams, irrigation ditches, ponds, and canals
 - Groundwater
 - Municipal water systems



If you use surface water



A sampling protocol shall be in place

Test water frequently for fecal coliforms and keep records of all water test results.

Take a close look at where your water lies in relation to potential sources of contaminants.

If you use ground water

- A sampling protocol shall be in place
- Ground water generally does not need to be tested as frequently as surface water
 - Consider variations in water quality throughout the season

FSMA – Produce Safety Rule Field Operation Water Quality

- Geometric Mean (126 cfu or less generic *E. coli* in 100 mL of water)
 - The average amount of generic *E. coli* in water
- Statistical Threshold (410 cfu or less generic *E. coli* in 100 mL of water)
 - Accounts for variability
 - The level at which 90% of samples are below the value

FSMA – Produce Safety Rule Field Operation Water Quality Assessment

- Surface Water
 - Initial Survey of at least 20 samples
 - Collected as close as is practicable to harvest over the course of 2-4 years
 - Used to determine Geometrical Mean and Statistical Threshold
 - Annual Survey thereafter of at least 5 samples per year
 - Used to update Geometrical Mean and Statistical Threshold
 - New samples plus the previous most recent 15 samples used to create a rolling dataset of 20 samples

FSMA – Produce Safety Rule Field Operation Water Quality Assessment

- Ground Water
 - Initial Survey of at least 4 samples
 - Collected as close as is practicable to harvest over the course of 1 year
 - Used to determine Geometrical Mean and Statistical Threshold
 - Annual Survey thereafter of at least 1 sample per year
 - Used to update Geometrical Mean and Statistical Threshold
 - New sample plus previous most recent 3 samples create rolling dataset of 4 samples

GAPs Recommended Draft Guidelines on Water Testing for The Produce Industry

Preharvest/harvest water that contacts EDIBLE portions of the produce (i.e., water used exclusively for irrigation and/or in pesticide sprays for products such as lettuce and other leafy greens.)

- Generic E. Coli <235 cfu*/100 ml sample of generic E. Coli for a single sample or <126 cfu/100 ml sample geometric mean.
- Where surface water is used for irrigation, monthly tests are recommended minimum frequency.

GAPs Recommended Draft Guidelines on Water Testing for The Produce Industry

Preharvest/harvest water that DOES NOT contact edible portions of the produce (such as irrigation water for melons, apples, etc.) such as that used in drip or furrow irrigation.

- Generic E. Coli <576 cfu*/100 ml sample of generic E. Coli for a single sample or <126 cfu/100 ml sample geometric mean.
- Where surface water is used for irrigation, monthly tests are recommended minimum frequency

If Tests of Preharvest/Harvest Water are Found to Exceed Recommendations

- Consider an alternative water source.
- Investigate what is causing the elevated microbial counts.
- Treat the water prior to use

Spray Water Quality

- **Use potable (drinking) water for pesticide sprays.**
- **When potable water is not available, test water quality and keep records.**
- **Low water volumes reduce risk.**



Flooding

- Crops in close proximity to soil can easily be contaminated by direct contact with flood waters.
- FDA considers ready-to eat crops (such as leafy greens and melons) that have contacted flood water to be adulterated.
- These crops are to be excluded from the food supply.



Flooding

- Consider potential contamination of crops from agricultural run-off (i.e. manure piles, etc.)
- Prevent cross-contamination by (equipment or humans) from flooded areas to non-flooded areas
- Allow flooded soils to dry sufficiently and be reworked prior to planting additional crops



GAPs Focus Areas

- ~~Worker Hygiene and Health~~
- ~~Water and Flooding~~
- Soil, Manure, and Compost
- Harvest/Post-Harvest

Soil, Manure, and Compost

Survival of Human Pathogens in Manure

- Pathogens have been reported to survive in manure for one year or longer.
- No one knows precisely how long manure borne pathogens survive after application to fields.
- Where it is not possible to maximize the time between application and harvest, raw manure should not be used.

Compost vs. Manure

Unless the compost has been produced under very strictly regulated circumstances then it is manure and should be treated as such.

So what makes manure compost?

C:N Ratio - between 25:1 and 40:1

If using windrow system, achieve between 131⁰ to 170⁰ F for at least 15 days.

Compost must be turned 5 times during the process.

Manage Manure and Unfinished Compost Carefully

- Isolate manure and unfinished compost from produce to prevent contamination



Prevent Contamination of Irrigation Water



Reduce Risk of Contamination

- Manure storage and treatment sites should be located as far as practical from fresh produce production and handling areas.
- Consider barriers or physical containment to secure manure storage or treatment areas where contamination from runoff, leaching, or wind spread is a concern.
- Eliminate or minimize the potential of recontaminating treated manure by birds, rodents, animals or with wind/waterborne contaminants.

Incorporate Manure

- Broadcast
- Disk



Note contamination from dust



Target Time of Application

- Apply manure in fall or after produce crop is harvested
- Do not apply to produce crops just prior to crop establishment - - but apply to non-food crops.
- Do not harvest fruits or vegetables until 120 days after application if fruits or vegetables contact soil. – 90 days if no soil contact.
- Keep records

Choose Appropriate Crops

- Avoid growing root and leafy green crops in the year that manure is applied
- Apply manure to perennial crops in the planting year only
- Keep records

Exclude Animals

Keep wildlife out of production areas as much as possible.



Keeping Animals Out

- Maintain domestic and farm animals away from production fields and packing facilities and establish physical barriers or vegetation to avoid animal entry. (Especially important in the field near harvest)
- Workers should not be allowed to bring dogs, cats or other domestic animals into the production field, packaging or storage facilities.
- Dead or trapped animals such as birds, insects, rats, etc. should be disposed of promptly in order to avoid attracting other animals. Proper disposal procedures are to bury or incinerate the animal.

GAPs Focus Areas

- ~~Worker Hygiene and Health~~
- ~~Water and Flooding~~
- ~~Soil, Manure, and Compost~~
- Harvest/Post-Harvest

Harvest/Post-Harvest

Harvest Considerations

- Ideally pick dry fruits or vegetables.
- Leave produce that has bird droppings on it.
- Clean and sanitize totes daily.
- Cool product quickly.
- Teach workers about proper handwashing and provide proper facilities.

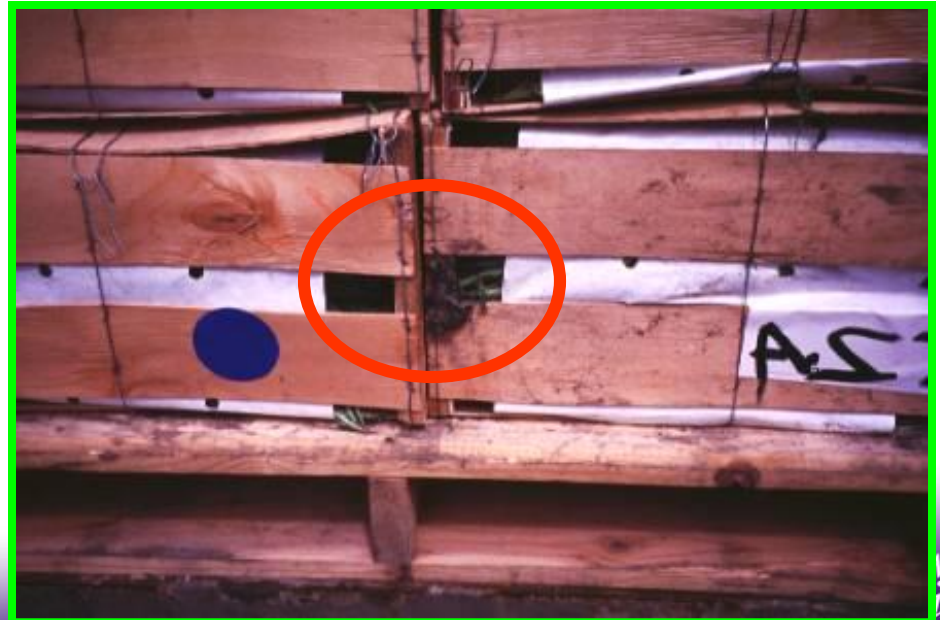


Punctured or Bruised Produce Provides the Entry for:

- **Plant Pathogens**
- **Foodborne Illness Pathogens**



Proper harvesting/culling is important to produce safety and quality.



**Field conditions may
increase risks**

Growers Are Innovating Their Own On-Farm Sanitation Routines

- Wash
- Rinse
- Sanitize



Avoid setting containers on the ground and allowing soil to splash up on them.

Develop a System for Maintaining Carton and Tote Sanitation



Sanitation in the Packinghouse

- Discard fruits and vegetables that fall on the floor
- No animals in packinghouse (dogs, cats, birds, rodents etc.)
- Keep flies and other insects out
- Prepare cartons **only** as needed
- Remove fruit and vegetable culls and debris promptly
- Enforce good worker hygiene

Sanitation in the Packinghouse: Accumulated Pathogens

- Microbes survive and grow on surfaces that remain wet (brush/sponge rolls; floors)
- Contact of plant material with surfaces:
 - waxes and plant sap accumulate
- Partially decayed plant material:
 - sticks to surfaces
 - is loaded with microbes
- Washing tubs and dump tanks
 - Pathogens can accumulate during packing

Temperature Management

- Low temperatures supplement good sanitation practices
- Avoid delays that postpone cooling
- Consider:
 - Time from harvest to packinghouse
 - Time from arrival to cooling of produce
 - Speed of cooling & final temperature

Temperature Management

- Storage and transport temperatures
 - Optimum temperatures for fruits and vegetables range from 32°F/0°C to 59°F/15°C
 - Most human pathogens grow slowly or not at all below 45°F/7°C
 - *Listeria monocytogenes* is a special concern in refrigerated environments
- Maintain records of temperature management

Guidelines for Postharvest Water

Postharvest Water, such as that used by processors or on-site sampling and cutting /processing. Any water that comes into contact with covered produce during or after harvest

- Water must meet standards for potable (drinking) water.

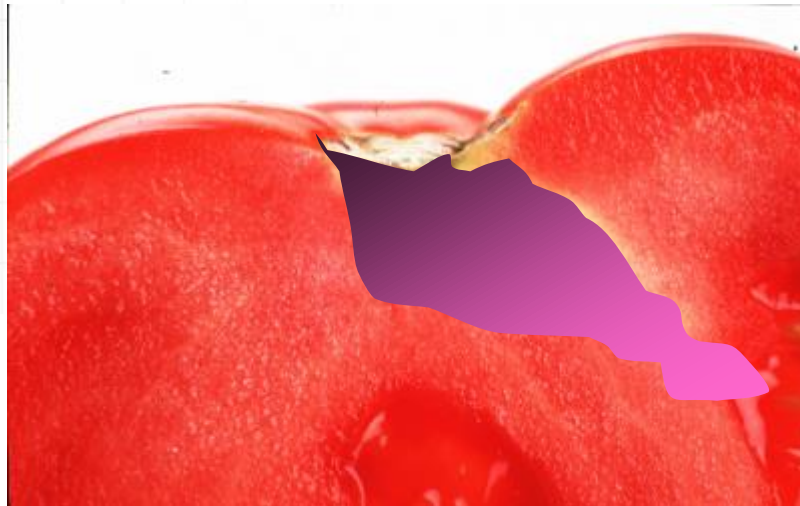
Wash Water Quality



- Use potable water for all produce washing, cooling, dipping, icing, and processing.
- Avoid water temperatures in dump tanks that are more than 10°F cooler than produce.

Bacteria can enter the stem scar with improper handling or wash water management

Fruit pulp must be $< 10^{\circ}\text{F}$ warmer than water temperature to prevent infiltration.



Warm fruit contracts in cold water pulling water and microbes into the fruit.

Protecting Produce on the Move

- **Inspect trucks prior to loading to insure cleanliness and proper refrigeration.**
 - **Dust, splash up contamination**
- **Identify prior loads hauled in the truck.**
- **Trucks that have hauled raw animal products should be avoided due to the risk of cross contamination.**

Example: Transportation Vehicles

- Avoid transporting produce in same trailers used for animal transportation
- Consider how well product is protected from environmental contamination (i.e., road debris) during transportation
- Shipping containers and vehicles must be clean and sanitary
- Routinely inspect shipping containers/trailers for condition, cleanliness and repair



GAPs Focus Areas

- ~~Worker Hygiene and Health~~
- ~~Water and Flooding~~
- ~~Soil, Manure, and Compost~~
- ~~Harvest/Post-Harvest~~

Recap

- FSA Produce Safety Rule
 - Exemptions
 - Qualified Exemptions
 - May be revoked
 - May be reinstated
- GAPs Certification
 - Food Safety Plan
 - 3rd Party Audit
- Good Agricultural Practices
 - Every Producer's Responsibility

Resources

- K-State Produce Safety Toolkit
 - <http://www.ksre.k-state.edu/foodsafety/produce/index.html>
- FDA Key Requirements – Produce Safety Rule
 - <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472887.pdf>
- Produce Safety Alliance
 - <https://producesafetyalliance.cornell.edu/>
- Federal Register Final Rule – Produce Safety
 - <https://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-28159.pdf>

Questions?

Thank You