



# **What Cabbage Growers Need to Know about FSMA Produce Safety Rule**



New York State Expo  
January 19, 2016



Elizabeth A. Bihn, Ph.D.  
Cornell University



# Topics

- What do you want to know about the Food Safety Modernization Act (FSMA) Produce Safety Rule?
- Nitty Gritty Produce Safety Rule Details
- Produce Safety Alliance Training Overview
- Questions and Discussion



# Covered Produce

- Cabbage is a covered commodity
  - There are lots of other covered produce items, but this is a cabbage session so I felt it was ok to skip over the others



- The term “covered produce” is important to know because this is used throughout the rule



# Qualified Exemptions

1. During the previous 3-year period, more than half of the average annual monetary value of the food the farm sold was directly to qualified end-users
  - a) the consumer of the food (consumer does not include a business); or
  - b) a restaurant or retail food establishment that is located:
    - i. In the same State or the same Indian reservation as the farm that produced the food; or
    - ii. Not more than 275 miles from such farm

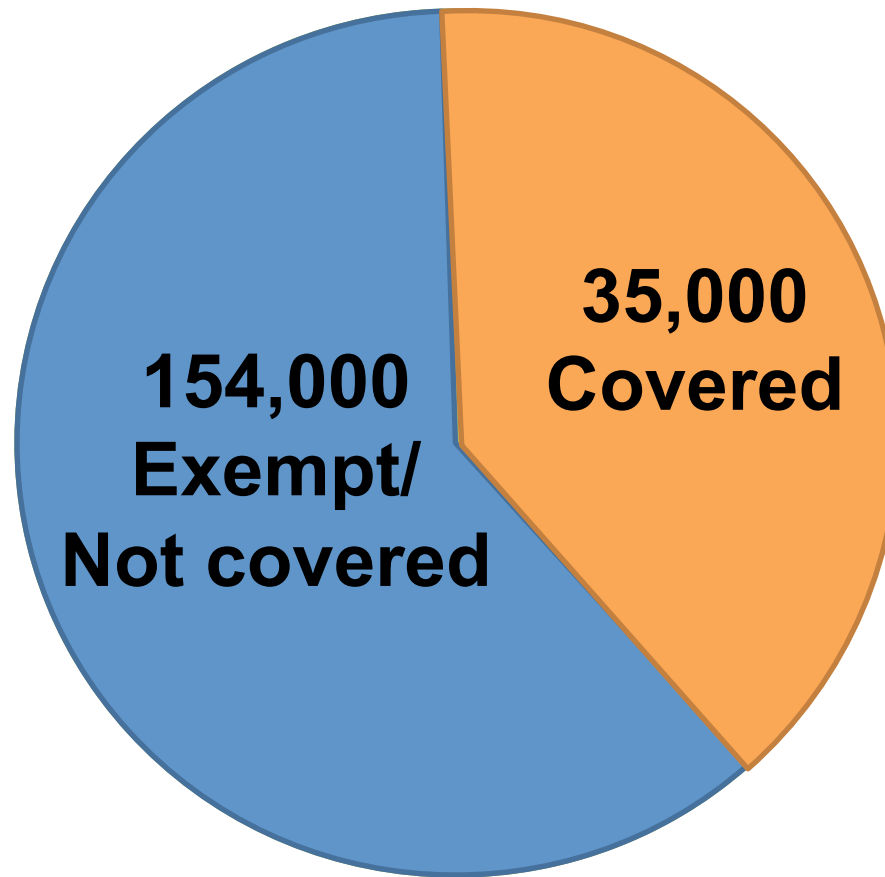
AND

2. The average annual monetary value of all food the farm sold during the 3- year period preceding the applicable calendar year was less than \$500,000





# Produce Farms Exempt From or Not Covered by the Rule



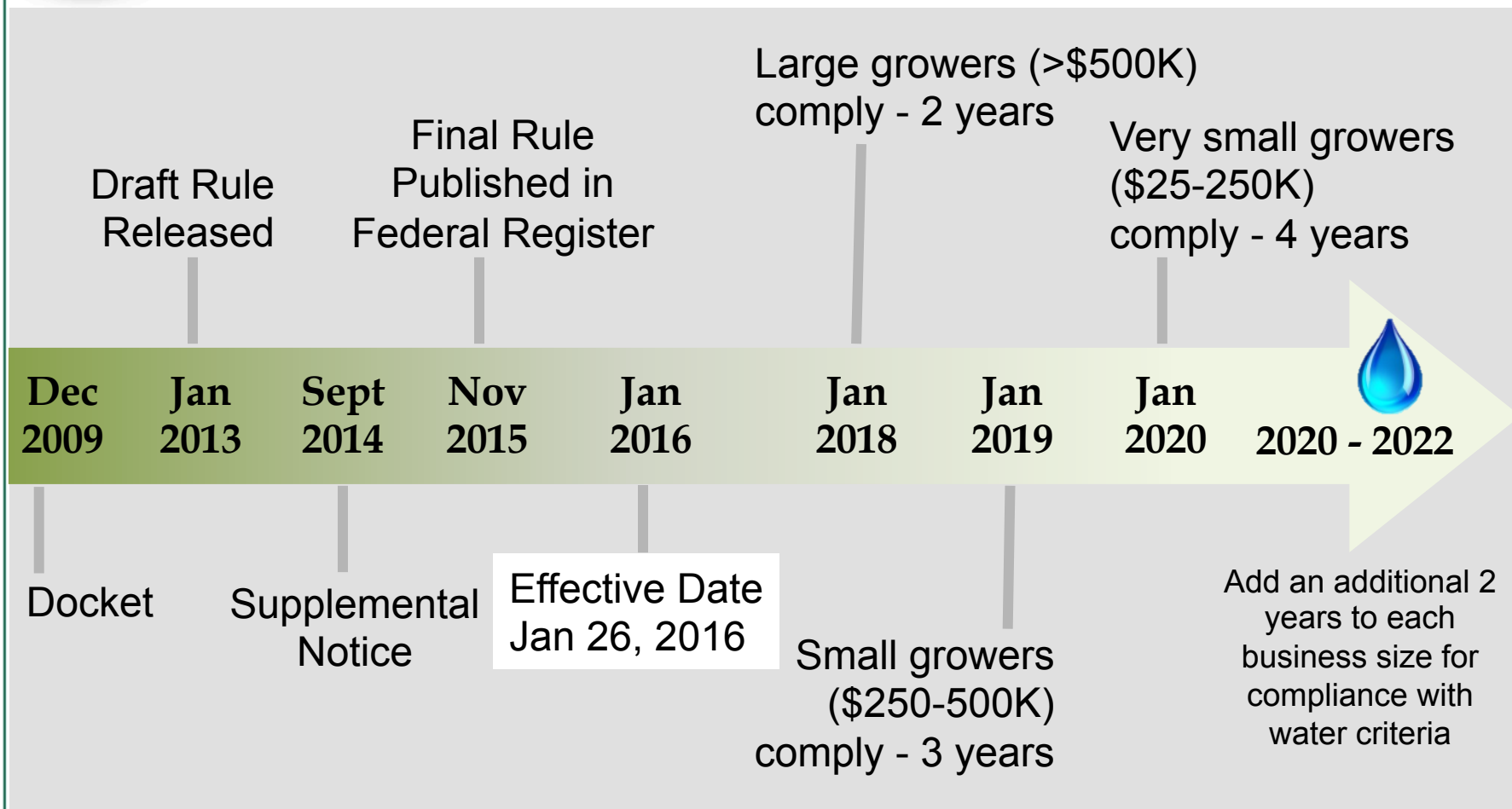


**Growers may be exempt from the regulation, but not from the market place.**





# FSMA Produce Safety Rule Time Frame





# Food Safety Preventive Controls for Human Food Rule

- **Will growers fall under two regulations?**
  - **Preventive Controls Rule:** Focus on the manufacturing, processing, packing or holding of human food
  - Initial concern that some growers would fall into this regulation in addition to the produce rule
  - New definitions of farm, sales, holding, and packing activities have helped to clarify





*Preventive Controls for Human Food rule expands it further to cover two kinds of farming operations: **Primary production**  
**Secondary activities***

## Primary Production Farm

- An operation under one management in one general, but not necessarily contiguous, location
- Devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities
  - The definition has been expanded to include operations that just grow crops and operations that just harvest crops.

# Primary Production Farm

- In addition to these activities, a primary production farm can:
  - Pack or hold RACs (regardless of who grew or raised them)
  - Manufacture/process, pack, or hold processed foods so long as:
    - all such food is consumed on that farm or another farm under the same management; or
    - the manufacturing/processing falls into limited categories

# Secondary Activities Farm

- An operation not located on a primary production farm that is devoted to harvesting, packing, and/or holding RACs.
- The primary production farm(s) that grow, harvest, and/or raise the majority of those RACs **must own or jointly own a majority interest in the secondary activities farm.**
- The definition also allows certain, limited additional manufacturing/processing, packing, and holding
  - Same as those for a primary production farm



# FSMA Produce Safety Rule

## Nitty Gritty Details

### 21 CFR Parts 11, 16, and 112

- Part 11: Electronic Records and Electronic Signatures
- Part 16: Regulatory Hearing Before the FDA
- **Part 112: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption**

Federal Register, Vol. 80, No. 228, November 27, 2015

Docket No. FDA 2011-N-0921





# Subparts of 21 CFR Part 112

- A – General Provisions
- B – General Requirements
- C – Personnel Qualifications and Training
- D – Health and Hygiene
- E – Agricultural Water
- F – Biological Soil Amendments of Animal Origin and Human Waste
- I – Domesticated and Wild Animals
- K – Growing, Harvesting, Packing, and Holding Activities
- L – Equipment, Buildings, Tools, and Sanitation
- M – Sprouts
- N – Analytical Methods
- O – Records
- P, Q, R – Variances, Compliance, and Withdrawal of Qualified Exemptions



## Training Requirements: Supervisors

- § 112.22(c) At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the FDA

**The PSA Curriculum will meet this requirement!**





# Training Requirements: Field Harvesters

- Persons who conduct harvest activities must be trained on the following:
  - Recognizing when covered produce must not be harvested because of contamination risks
  - **Inspecting** harvest containers and equipment to ensure that they are functioning properly, clean and maintained so as not to become a source of contamination
  - **Correct** and **report** any problems with harvest containers or equipment





# Required Hygienic Practices

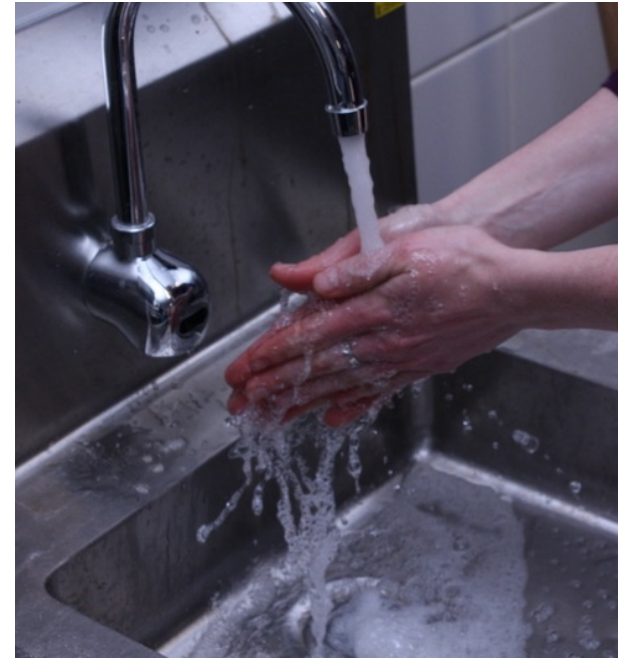
- Maintain personal cleanliness
- Avoid contact with animals other than working animals and take action to minimize likelihood of contamination of covered produce
- If using gloves, maintain in an intact and sanitary manner and replace when necessary
- Remove or cover hand jewelry that cannot be cleaned and sanitized when covered produce is manipulated by hand; and
- Do not eat, chew gum, or use tobacco products in the area used for a covered activity (drinking beverages is permitted)
- Hand washing (see next slide)





# Hand Washing Requirements

- Wash hands thoroughly using soap (or other effective surfactant) and water, dry hands thoroughly using single-service towels, sanitary towel service, electric hand dryers or other hand drying devices:
  - Before starting work
  - Before putting on gloves
  - After using the toilet
  - Upon return to the work station after breaks
  - As soon as practical after touching animals or animal waste
  - At any other time workers hands may become contaminated





# Training Requirements: Farm Workers



- All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are supervisors of said personnel, **must receive adequate training per person's duties**, upon hiring and periodically thereafter, at least once annually
- Training must be conducted in a manner that is **easily understood** by personnel being trained



# Visitors



- **Growers must:**
  - Make visitors aware of the farm's food safety policies
  - Provide access to toilet and hand washing facilities
- **Other key information for visitors should include:**
  - Areas of the farm they are allowed to visit
  - The importance of not visiting the farm when ill
  - How to wash their hands
  - Instructions to keep pets at home



# Untreated Soil Amendments

- Untreated biological soil amendments of animal origin are considered high risk since they have not been treated to reduce or eliminate pathogens
- All of the following soil amendments would be considered untreated:
  - Raw manure
  - ‘Aged’ or ‘stacked’ manure
  - Untreated manure slurries
  - Untreated manure teas
  - Agricultural teas with supplemental microbial nutrients
  - Any soil amendment mixed with raw manure







# Minimum Application Intervals

- There are currently no application intervals for raw manure outlined in the Produce Safety Rule
- **Untreated Soil Amendments**
  - FDA is currently pursuing further research to support application intervals for raw manure
- **Treated Soil Amendments**
  - 0 day application interval for compost treated by a scientifically validated process





# Inspect Agricultural Water Sources and Water Distribution Systems

- Water can be contaminated at the source, or it can become contaminated in the distribution system
- Map and describe all water distribution systems
- Water sources and distribution systems **must** be inspected at least annually
- Keep water sources free of debris, trash, domesticated animals, and other hazards





# What Water Must Be Tested?

- Agricultural water used with a direct water application method to covered produce
  - **Agricultural water** means water used in covered activities on covered produce where water is intended to, or is likely to, contact **covered produce or food contact surfaces**.
  - **Direct water application method** means using agricultural water in a manner whereby the water is intended to, or is likely to, contact **covered produce or food contact surfaces** during use of the water.
  - **Covered produce** means produce that is subject to the Produce Safety Rule. The term “covered produce” refers to the harvestable or harvested part of the crop



# Production Water Quality Criteria

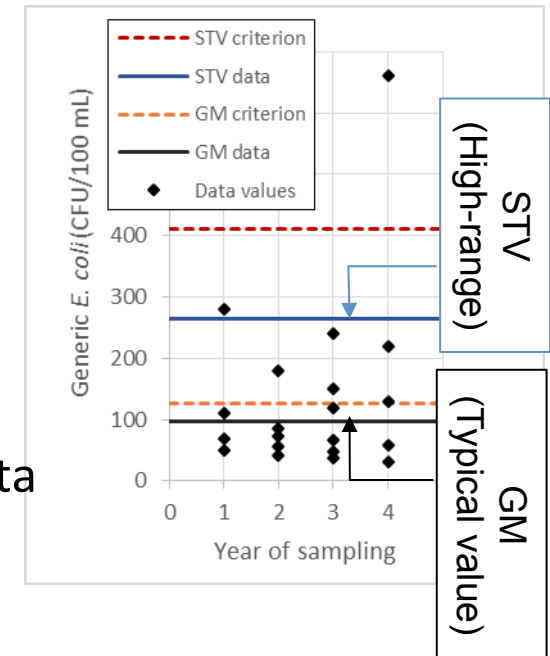
- Apply to water used with a direct water application method to covered produce
  - Each source of production water must be tested to evaluate whether it meets the criteria:
    - **126 or less** colony forming units (CFU) generic *E. coli* per 100 mL water geometric mean (GM)
- AND**
- **410 or less** CFU generic *E. coli* per 100 mL water statistical threshold value (STV)



# Geometric Means and Statistical Threshold Values

- Test results must be used to calculate Geometric Means and Statistical Threshold Values to compare to criteria in the FSMA Produce Safety Rule
  - The geometric mean (GM) is a log-scale average, the “typical” value
  - The statistical threshold value (STV) is a measure of variability, the expected “high range” value (modeled 90% percentile)
  - The STV is calculated using log-transformed data  

$$\text{Log(STV)} = \text{Average} + 1.28 * \text{Standard deviation}$$



**There will be tools to help you calculate this! Do not panic!**



# Using Surface Water Quality Profiles

## **START:**

Establish water quality profile  
At least 20 samples over 2-4 years



## **ANNUALLY AFTER START:**

Collect at least 5 samples for analysis  
Add to 3 prior years of profile data to  
create a rolling 4-year data set



## **IF YOUR WATER CHANGES:**

If the water quality profile no  
longer represents the quality of the  
water source, or you change  
sources, establish a new profile

## **IF YOUR PROFILE DOES NOT MEET GM OR STV CRITERIA:**

As soon as practicable and no later  
than the following year, discontinue  
use of the water unless an allowed  
corrective measure is applied



## **ALLOWED CORRECTIVE MEASURES:**

1. Apply a time interval to allow die-off or removal
2. Re-inspect the water system, identify problems, and make necessary changes
3. Treat the water







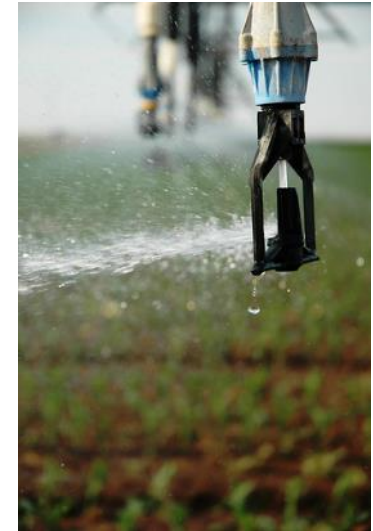
# Corrective Measures

- Three types of corrective measures are allowed if your water source does not meet water quality criteria:
  1. Apply a time interval
    - i. In-field die-off
    - ii. Die-off during storage and/or removal during activities such as commercial washing
  2. Re-inspect the water system, identify problems, and make necessary changes
  3. Treat the water



# Water Application and Timing

- Risks from production water may be reduced by maximizing the time between application and harvest
  - One legal corrective measure for water quality is use of a microbial die-off rate of 0.5 log per day during an application interval of four consecutive days or less
  - 0.5 log is approximately 68%
  - Four days results in 2-log (99%) calculated die off
- This is important if your initial water quality profile does not meet GM and STV criteria!*





# Treating Production Water

- Production water may be treated if there is reason to believe the water is not safe for its intended use
  - Any chemicals used to treat water must be EPA registered and labeled for use in production water
  - Non-chemical treatments, called pesticide devices by EPA, may be used if they adequately reduce microbial risks
    - Filter units, UV light units, ozonator units
- You should avoid water treatments that may have negative environmental and soil quality impacts
- You must keep records of all treatment monitoring done



# Water Quality Criterion for Harvest and Postharvest Activities

- Water used for the following must have no detectable generic *E. coli* per 100 mL sample
  - Direct contact with covered produce during or after harvest
  - Direct contact with food contact surfaces
  - To make ice
  - For hand washing
- Untreated surface water may not be used for these purposes





# Key Water Quality Variables

- Quality at start of use
  - No detectable generic *E.coli* in 100 mL of sample
- pH
  - Can impact sanitizer effectiveness
- Temperature
  - **Must be** monitored to minimize potential for infiltration
- Turbidity
  - Can be used to manage water change schedule





# Agricultural Water Records

- Document results of all water tests
- Document all monitoring and actions to reduce risks
  - Annual inspection of water system
  - Corrective measures taken, if any
    - Die-off and/or removal before and after harvest, including supporting calculations or scientific information to support alternatives used
    - Corrective actions taken during water system re-inspection, including protection of water sources from contamination, maintenance or other changes to the water distribution system
    - Monitoring of water treatments
- Scientific research used to support alternative indicators, criteria, or sampling frequencies





# Equipment and Tools

- Must use equipment and tools that are of **adequate design, construction, and workmanship** to enable them to be **adequately cleaned and properly maintained**
- **Seams** on food contact surfaces of equipment and tools must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms
- Must inspect, maintain, and clean and, when necessary and appropriate, **sanitize all food contact surfaces** of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce



# Grazing, Working and Intrusive Animals

- If animals **might reasonably** contaminate covered produce, growers must assess for evidence of potential contamination
- If **significant evidence** of potential contamination is found (such as **observation of animals, animal excreta, or crop destruction**), they must evaluate whether the produce can be harvested
- Take measures **reasonably necessary** during growing to assist later during harvest when growers must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a **known or reasonably foreseeable** hazard



# Mixed Crop Farms

- If you grow, harvest, pack or hold **excluded produce** and also conduct activities on **covered produce**, and **if the excluded produce is not grown, harvested, packed or held in accordance with the Produce Safety Rule**, you must take measures during these covered activities to:
  - Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and
  - Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce



## Some Harvesting Requirements

- **At a minimum**, identifying and not harvesting covered produce that is **reasonably likely** to be contaminated with animal excreta or that **is visibly contaminated** with animal excreta requires a **visual assessment** of the growing area and all covered produce to be harvested
- Must not distribute **dropped covered produce**. Dropped covered produce is covered produce that drops to the ground before harvest. Dropped covered produce does not include root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds).



# Cleaning vs. Sanitizing

*What is the difference and why does it matter?*

- **Cleaning:** Physical removal of dirt (soil) from surfaces by using clean water, soap (detergent), and scrubbing
- **Sanitizing:** Treatment of a cleaned surface with a sanitizer (such as chlorine) or other method (such as heat or steam) to reduce or eliminate microorganisms

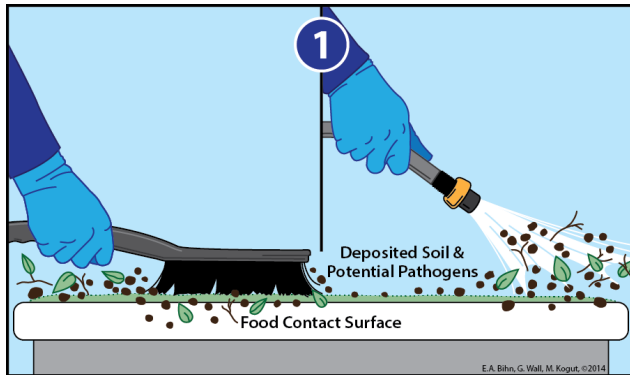
**Important point: You cannot sanitize a dirty surface.**

**Cleaning always comes first!**

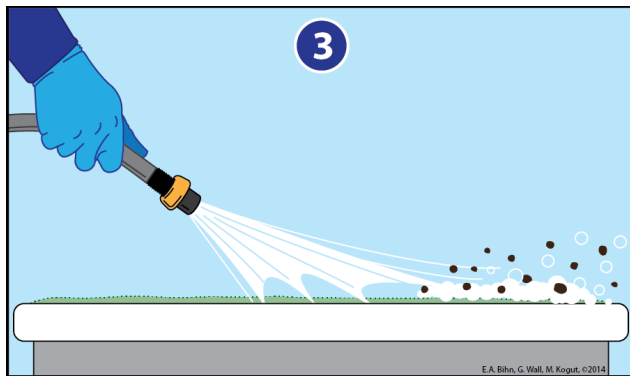
# Cleaning and Sanitizing



**Step 1:** Remove any obvious dirt and debris from the food contact surface



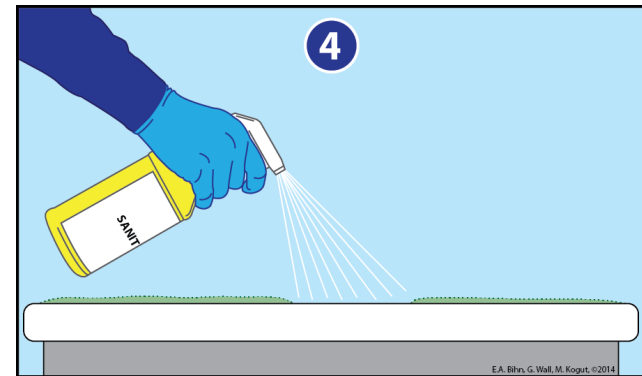
**Step 3:** Rinse the surface with clean water, making sure to remove all the detergent and soil



**Step 2:** Apply an appropriate detergent and scrub the surfaces



**Step 4:** Apply a sanitizer approved for use on food contact surfaces. Rinsing may be necessary. Let the surface air dry







# Transportation Requirements

- Equipment used to transport covered produce a) be adequately cleaned prior to transporting produce and b) adequate for use in transporting covered produce
- Use equipment such as pallets, forklifts, tractors, and vehicles such that they are **intended to, or likely to**, contact covered produce, they must do so in a manner that **minimizes the potential for contamination** of covered produce or food contact surfaces with known or **reasonably foreseeable hazards**.





# Pest Control Programs

- Must take measures to protect covered produce, food contact surfaces, and food-packing materials from contamination by pests, including routine monitoring for pests as necessary and appropriate.
- For fully-enclosed buildings, there **must** be measures in place to exclude pests.
- For partially-enclosed buildings, **must** take measures to prevent pests from becoming established or remove them, when present.





# The PSA Website

<http://producesafetyalliance.cornell.edu>



#### Welcome to the Produce Safety Alliance (PSA) website!

[Click here](#) to view the press release.

The PSA is developing a nationwide curriculum to increase understanding of the principles of Good Agricultural Practices (GAPs) and to facilitate the implementation of food safety practices on fresh fruit and vegetable farms and in packinghouses. [View the PSA's current Curriculum Modules and](#)

#### PSA-FDA Question & Answer Series

PSA-FDA Question & Answer Series on FSMA Proposed Produce Safety Rule. [Click here](#) to listen to all of the recordings from March 18–May 13, 2013.

[Click here for the PSA October newsletter.](#)



#### Stay up-to-date!

#### Produce Safety Alliance

Sign up for the Produce Safety Alliance listserve...



The listserve is a great way to receive the most current information related to educational and training

- You can even friend us on Facebook!



- Join the listserve!



- Contact us!

**Elizabeth A. Bihn, Ph.D., Director**

[eab38@cornell.edu](mailto:eab38@cornell.edu), 315.787.2625

**Don Stoeckel, Ph.D., Midwest Regional Extension Associate**

[dstoeckel@cornell.edu](mailto:dstoeckel@cornell.edu), 614.634.0884

**Produce Safety**  
ALLIANCE