

Preparing Your Farm for the Food Safety Modernization Act (FSMA)

NOFA/Mass Winter Conference
Worcester State University
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Lisa McKeag, UMass Extension & Michael Botelho, MDAR



WHO ARE WE?

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<https://ag.umass.edu/resources/food-safety/food-safety-for-farmers>

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WHO ARE YOU?

OUTLINE

- FSMA Intro
- CQP and the MA Produce Safety Inspection Program
- Food safety and small farms—why everyone should care
- Where to begin? Food safety tools and tips

All farms *should* use good agricultural practices (GAPs).

Covered farms *must document* that they are using GAPs

WHAT ARE GAPS?

Good Agricultural Practices(GAPs)

Practices that minimize the occurrence of microbial contamination of fruits and vegetables



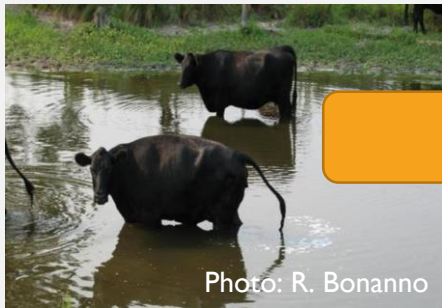
Worker health & hygiene

Photo: R. Bonanno



Livestock & wildlife

Photo: wikipedia



Water quality

Photo: R. Bonanno



Storage, transportation,
and traceability

Photo: R. Hazzard



Manure & compost

Photo: R. Bonanno



Field & packing house
sanitation

Photo: R. Hazzard

WHAT ARE GAPS?

- Based on FDA Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (1998).
- **Third Party Audit Programs**
 - Public and Private Providers
 - **USDA GAPs/Harmonized GAPs/LGMA**
 - PRIMUS GAPs/Global GAPs
 - Voluntary – driven by buyers
 - Expensive, lots of recordkeeping



FSMA

WHAT NECESSITATED FSMA?

- Outbreaks despite FDA guidance and voluntary audit programs. **Guidance not enforceable.**
- Increased # of outbreaks associated with fresh produce
- Several highly-publicized cases: Leafy greens, cantaloupe, peppers
- Increased consumption of fresh produce
- Largest farms with long distribution chains considered greatest risk

THE FOOD SAFETY MODERNIZATION ACT (FSMA)



- Law is part of the Food, Drug and Cosmetic Act (1938)
- Gives FDA new authority to oversee how food is grown, harvested and processed
- Focus is on PREVENTION instead of response
- Science-based. Ongoing research to identify hazards, degrees of risk, and strategies to mitigate.

7 RULES IN FSMA

1. Accredited Third-Party Certification
2. Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals
3. Mitigation Strategies to Protect Food Against Intentional Adulteration
4. Preventive Controls for Food for Animals
5. Preventive Controls for Human Food
6. Sanitary Transportation of Human and Animal Food
7. **Standards for Produce Safety = The Produce Safety Rule**

THE PRODUCE SAFETY RULE

- Final Rule = Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
- Published in the Federal Register on November 27, 2015
- **The PSR**

Where to find it: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

Verizon 10:55 AM fda.gov

back to Guidance & Regulation

FSMA Final Rule on Produce Safety

SHARE TWEET EMAIL

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

[Produce Safety Standards under the FSMA Main Page](#)

[Stay connected with FSMA E-mail updates!](#)

View the Final Rule Contents in the Federal Register Notice

Below is a fact sheet provided by FDA.

About the Final Rule

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Office of the Federal Register

FEDERAL REGISTER The Daily Journal of the United States Government

Rule

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

A Rule by the Food and Drug Administration on 11/27/2015

ACTION Final Rule.

SUMMARY To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, the Food and Drug Administration (FDA or we) is establishing science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. FDA is establishing these standards as part of our implementation of the FDA Food Safety and Modernization Act. These standards do not apply to produce that is rarely consumed raw, produce for personal or on-farm consumption, or produce that is not a raw agricultural commodity. In addition, produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance is eligible for exemption from the requirements of this rule. The rule sets forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. We expect the rule to reduce foodborne illness associated with the consumption of contaminated produce.

LEGAL DISCLAIMER

Publication Date: Friday, November 27, 2015

Agencies: Department of Health and Human Services
Food and Drug Administration

Dates: This rule is effective January 26, 2016. The effective date of Sec. 117.59(e)(2), 117.6, 117.405(c), 117.410(d)(2)(i), 117.430(b), and 117.475(c)(13) published September 17, 2015 (80 FR 55008), is January 26, 2016. The effective date of Sec. 507.12(a)(1)(i), 507.105(c), 507.110(c)(2)(i), 507.130(d), and 507.175(c)(13) published September 17, 2015 (80 FR 56170), is January 26, 2016. See section XXIV of this document for the compliance dates. The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register as of January 26, 2016.

Effective Date: 01/26/2016

Entry Type: Rule

Action: Final rule.

Document Citation: 80 FR 74353

Page: 74353-74568 (216 pages)

UNIFIED AGENDA Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

15 actions from January 16th, 2013 to October 2015

September 29th, 2014 December 15th, 2014 October 2015

THE PSR: SCOPE

- Science-based, minimum standards
- Raw agricultural commodities
- Includes the growing, harvesting, packing and holding of produce.
- Focuses on biological hazards
- Applies to both domestic and imported produce.

THE PSR: **COVERAGE & EXEMPTIONS**

- Farms over grossing 500k (all food) fully covered by the rule (3 year average)
- Farms below 25k (just produce) are fully exempt
- Qualified exemptions for farms meeting certain criteria
- The rule does not apply to certain, non-covered produce = rarely consumed raw

THE PSR: NOT PRESCRIPTIVE

Regulatory language, few prescriptive instructions on how to comply with the law.

Example:

§112.128 What requirements apply regarding pest control in buildings?

(a) You must take those measures *reasonably necessary* to protect covered produce, food contact surfaces, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate.




THE PSR: **ADAPTABLE**

- Research, guidance and risk assessments
- Regional research
- Training and Education and alternative curriculum
- Variances and Alternative Practices
- **Will be amended with new information**

FDA: “We will **educate** before and while we regulate”

IMPORTANT FDA ANNOUNCEMENTS

- **Agricultural Water Compliance Dates**
 - Proposed rule
 - additional two to four years (for produce other than sprouts)
- **Water Testing Methods**
 - Method 1603
 - 8 additional methods
- **Produce Farm Inspections**
 - Largest farms expected to be in compliance by 2018
 - Inspections won't begin until **2019**
 - more education, training, and outreach

Business Size	 Compliance Dates for Sprouts	 Compliance Dates For Most Produce	 Water Related Compliance Dates ¹	Compliance Date for Qualified Exemption Labeling Requirement ²	Compliance Date for Retention of Records Supporting a Qualified Exemption
All other businesses (>\$500K)	1/26/17	1/26/18	1/26/22	1/1/2020	1/26/16
Small businesses (>\$250K-500K) ³	1/26/18	1/28/19	1/26/23		
Very small businesses (>\$25K-250K) ⁴	1/28/19	1/27/20	1/26/24		

¹ According to the [Proposed Rule](#) issued 9/13/17, Compliance dates for Subpart E, Agricultural Water, allow an additional four years.

² A farm eligible for a qualified exemption must notify consumers as to the complete business address of the farm where the food is grown, harvested, packed, and held. ³ A farm is a small business if, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than \$500,000.

⁴ A farm is a very small business if, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than \$250,000.

Before the compliance date, every covered farm that does not qualify for an exemption must have a supervisor (such as a farm owner/operator) complete a standardized food safety training program. You can find out more about food safety training from the Produce Safety Alliance. <https://producesafetyalliance.cornell.edu/training>

Revised 10/09/17

THE PSR: STATUTORY AUTHORITY IN MASSACHUSETTS

- Massachusetts cooperative agreement with the FDA
- Each State has a different lead authority
- MA Produce Inspection Program, adopting FSMA standards under State authority
- Also establish statutory support for non-covered crops
- MA state rule – supplement to budget bill

CQP AND THE MA PRODUCE INSPECTION PROGRAM

Michael A. Botelho (PI)

Program Director, MDAR Farm Food Safety, Market Access and Certification

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Alexandra Hachem

Produce Safety Program Coordinator, MDAR
Education, Research and Technical Assistance

Steven Pilis

Program Director, MDAR
Program Operations

- 3 inspectors hired, 2 more projected

Laura Maul (Co-PI)

Grants Program Coordinator, MDAR
AEEP, AFSIP Grants Manager



WHAT IS CQP?



- Commonwealth Quality Program
- Introduced in 2009
- “GAP-light” – reduced record-keeping, no cost
- On-farm support, technical assistance
- Market access, brokering, working with buyers
- Collaboration with UMass
- Native Law, Environmental Sustainability

WHAT IS CQP?



- Designed to educate, assist in change management
 - Voluntary
 - Classroom education
 - Boots on the ground
 - On-farm technical support = pre-audits
 - Support dialogue and transparency between buyer and producer
 - Provide Grant assistance (AFSIP)

CQP & FSMA

- Integrate CQP audit checklist with FSMA Produce Safety Rule & USDA/Harmonized GAPs
- MA Only:
 - Require a structured Farm Food Safety Plan
 - SOPs for risk commodities/practices
 - Water distribution map
- Classroom education (PSA Curriculum) and on-site technical assistance (OFRR)
- One scheduled audit with follow-ups scheduled
- Update environmental standards

CQP & FSMA

- Produce Inspections = Outbound support
- CQP audits for Market Access = Inbound support
- USDA Harmonized GAP Support
- Farm registry

CQP & FSMA

- MDAR updating website – not active now!
 - Resources
 - Templates
 - On-line farm registration
 - Regional contact information for technical support
- For now:

Michael Botelho

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PRODUCE SAFETY INSPECTIONS

- Initially target covered farms and those identified as high priority
- Produce Sales (Average Annual Revenue)
 - Greater than \$500 thousand
- Commodity Type (High Risk)
- Farm Size (Acreage)
- Agricultural Water Use





Commonwealth Quality & MA Produce Inspection Program

Covered by FSMA

Buyer requirement
Want technical support

outbound

inbound

1. Apply – complete CQP application/farm registration
2. CQP Pre-audit (=On-farm Readiness Review)
3. Technical support & grants
4. **Inspection** or **audit**
5. Certification – renew annually, continued support

required

request

<http://www.mass.gov/eea/agencies/agr/about/divisions/afsip.html>

Laura Maul, laura.maul@state.ma.us, 617-626-1739

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[EEA Home](#) > [Agencies](#) > [Department of Agricultural Resources](#) > [Ag Food Safety Improvement Program \(AFSIP\)](#)

Agricultural Food Safety Improvement Program (AFSIP)



The Agricultural Food Safety Improvement Program (AFSIP) supports agricultural produce operations that are looking to upgrade their food safety practices. Practices that help the operation to maintain or to increase their market access while reducing food safety risks. Participants selected to participate in the program will be reimbursed up to \$25,000 or 75% of their total project costs.

AFSIP will fund practices that help minimize the risk of microbial contamination and food-borne illnesses. In addition, eligible upgrades will increase competitive market access by meeting buyer demands for demonstrated practices that work towards protecting public health and food safety.

Some examples of projects include wildlife fencing, packing shed walls, ceilings and light fixtures, field harvest systems, hand washing sinks, portable restrooms, drainage systems, and water systems.

Eligibility and Applying

To be eligible for funding the applicant must be in good standing with the Department and other local and state regulatory agencies. Additional consideration will be offered to applicants who are participants in the [Commonwealth Quality Program \(CQP\)](#), and/or are currently audited under a [Good Agricultural Practices \(GAP\)](#) certifier. There is no minimum size requirement; however, projects that address significant food safety concerns are more likely to receive funding.

Contact

Laura Maul
laura.maul@state.ma.us
617-626-1739

Information

- [Division of Agricultural Conservation & Tech Assistance](#)
- [Agricultural Business Training Program \(ABTP\)](#)
- [Farm Technology Review Commission \(FTRC\)](#)
- [Grants and Funding Programs](#)
- [Land Use](#)

FOOD SAFETY AND SMALL
FARMS—WHY EVERYONE
SHOULD CARE

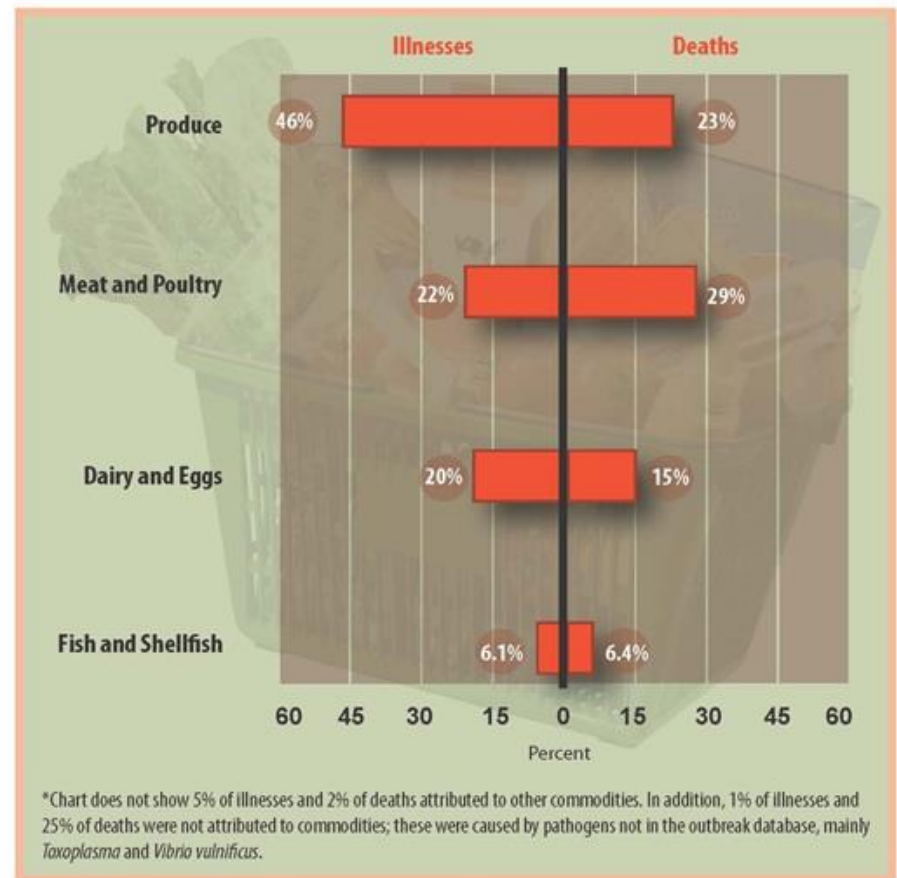
All farms *should* use good agricultural practices (GAPs).

Covered farms *must document* that they are using GAPs

WHY SHOULD I CARE?

- Only unregulated major link in the food chain
- In CDC study, produce accounted for nearly half of all reported food-borne illnesses

Figure 1. Contribution of different food categories to estimated domestically-acquired illnesses and deaths, 1998-2008*



Source: Painter JA, Hoekstra RM, Ayers T, Tauxe RV, Braden CR, Angulo FJ, Griffin PM. Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998–2008. *Emerg Infect Dis* [Internet]. 2013 Mar [date cited]. <http://dx.doi.org/10.3201/eid1903.111866>

WHY SHOULD I CARE?

- 2011 **Fresh Strawberries**, E.coli O157:H7, small Oregon Strawberry Farm
 - 15 total ill, 7 hospitalized and 1 death of elderly
 - Deer feces isolated as the source.
 - Sold at farmers markets and farm stand



- December, 2017, multistate outbreak of Shiga toxin-producing [E. coli O157:H7](#) infections in 13 states, including CT, NH, NY, VT
 - 41 cases, 17 hospitalized, 1 dead in Canada—outbreak likely linked.
 - Canadian authorities traced outbreak to **romaine lettuce**.
 - Active outbreak

FOOD SAFETY IS IMPORTANT

Protecting your business...

- Your liability
- Your reputation
- Your customers
- The local food system



Photo: <https://www.stir.ac.uk/ccwp/>

FOOD SAFETY IS IMPORTANT

Your LIABILITY...

- **Pritzker Hageman Wins \$7.55 Million Verdict for Child with HUS E. coli**

“There were no handwashing stations, warning signs, or any other measures to prevent transmission of disease at the facility. **The business owners claimed they had no idea that children could get sick by touching animals.** They did not take preventive measures because they didn’t think the setting was a risk to children.”

FOOD SAFETY IS IMPORTANT

- Expansion of local production
- Between 2007 and 2012, Massachusetts was one of only 10 states in US to see an increase in the number of farms and acreage of land in farming.
- Massachusetts has a growing number of beginning farmers
- Large # of new growers in the state not reached by food safety training, maybe not familiar with the need for good agricultural practices for market access and regulatory compliance
- Small farms not generally implicated in foodborne illness outbreaks, BUT evidence that many cases of foodborne illness go unreported, and estimates of actual numbers are much higher than the official count





Increased access to
vulnerable
populations

MASSACHUSETTS
Farm to School
PROJECT

MORE THAN
\$8 MILLION
SPENT ON LOCAL
FOOD BY HEALTH
CARE FACILITIES
IN 2015

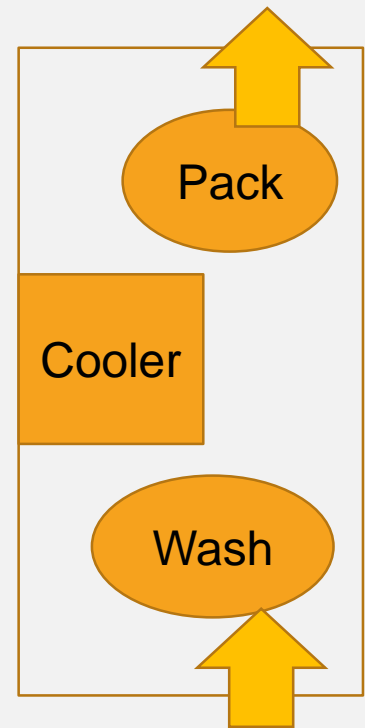
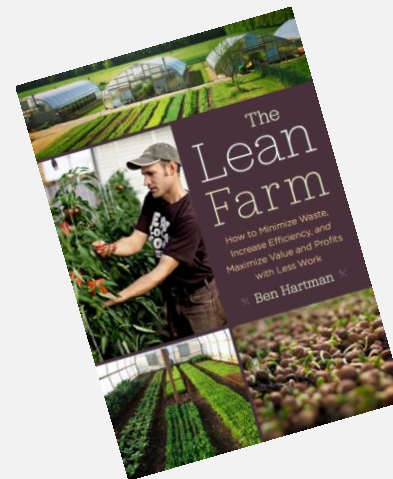
FARM to INSTITUTION
NEW ENGLAND



Photo: patch.com

CAPITALIZE ON IMPROVEMENTS

- Higher quality product (human pathogens and plant pathogens thrive in similar environments)
- Better training = higher quality work
- Increased efficiency
- Access to grant funds for improvements
- Access to new markets
- Public trust



WITHDRAWAL OF EXEMPTIONS FOR SMALL FARMS

- A farm's qualified exemption may be withdrawn as follows:
 - If there is an active investigation of an outbreak of foodborne illness that is directly linked to the farm, or
 - If FDA determines it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions associated with the farm that are material to the safety of the farm's produce that would be covered by the rule.

SUMMARY: WHY CARE

- Liability is ultimately yours
- Lack of GAPs training among beginning farmers, those not compelled by buyers
- Greater access to vulnerable populations
- Improved quality and efficiency
- FSMA exemptions can be withdrawn

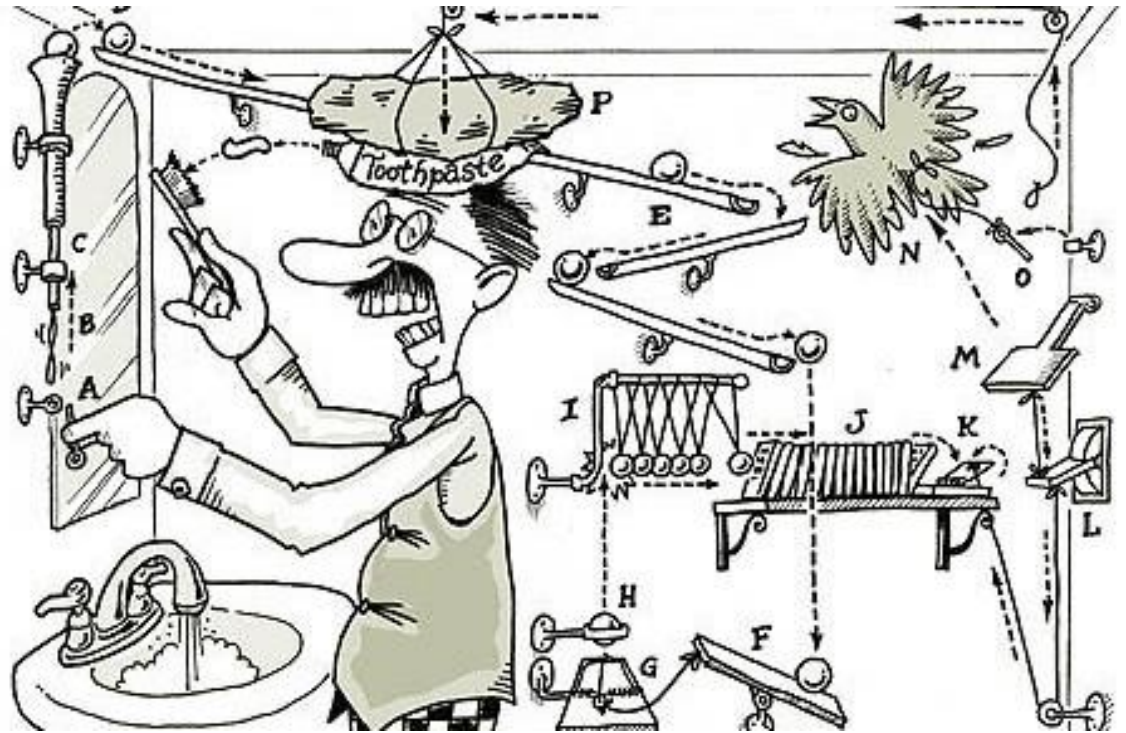
It's a cultural shift—that's
what you need to start
implementing now!

**WHERE TO BEGIN?
PRACTICAL STEPS**

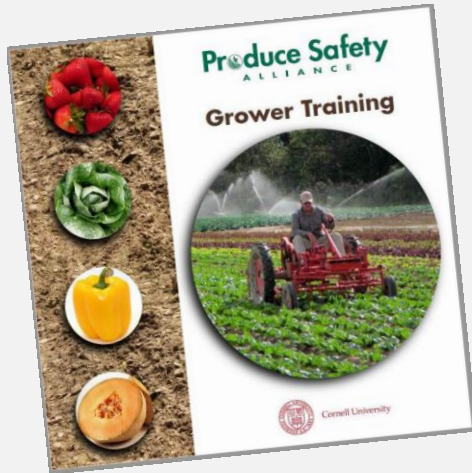
1. Attend a training
2. Figure out if you're covered
3. Participate in Commonwealth Quality (inbound support)
4. Test your water
5. Write SOPs for your routine processes
6. Train your employees on hygiene and farm practices
7. Assess risks
8. Keep records

“THE
PERFECT
IS
THE
ENEMY OF
THE
GOOD.”

- VOLTAIRE



ATTEND A TRAINING



HOLYOKE, Feb 6

TOPSFIELD, Feb 13

LENOX, March 13

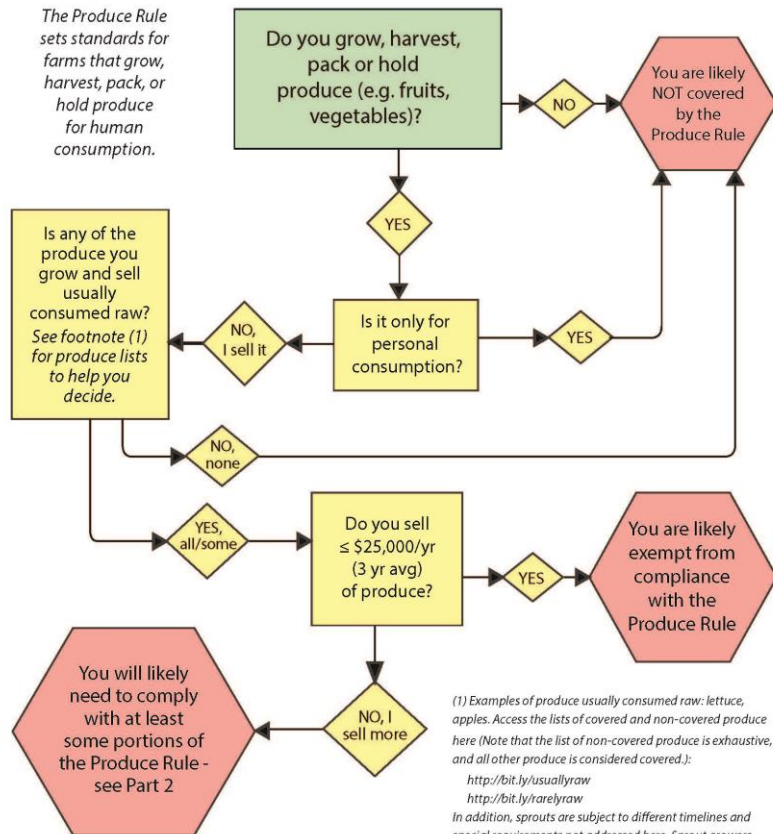
WAREHAM, March 20

The PSA Grower Training Course is one way to satisfy the FSMA Produce Safety Rule requirement outlined in § 112.22(c) that requires **‘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 Food and Drug Administration.’

FIGURE OUT IF YOU'RE COVERED

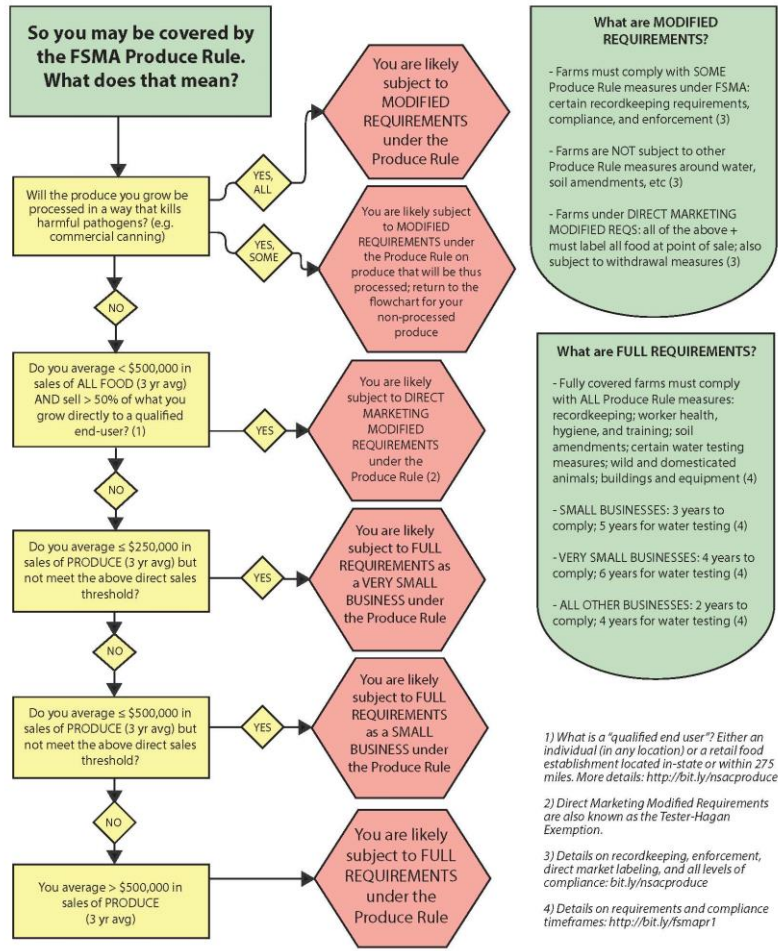
Am I Affected by the FSMA Produce Rule?

The Produce Rule sets standards for farms that grow, harvest, pack, or hold produce for human consumption.



(1) Examples of produce usually consumed raw: lettuce, apples. Access the lists of covered and non-covered produce here (Note that the list of non-covered produce is exhaustive, and all other produce is considered covered.): <http://bit.ly/usuallyraw> <http://bit.ly/rarelyraw> In addition, sprouts are subject to different timelines and special requirements not addressed here. Sprout growers should visit the Sprout Safety Alliance for more information: http://www.iit.edu/ifsh/sprout_safety

The FSMA Produce Rule - Part 2



What are MODIFIED REQUIREMENTS?

- Farms must comply with SOME Produce Rule measures under FSMA: certain recordkeeping requirements, compliance, and enforcement (3)
- Farms are NOT subject to other Produce Rule measures around water, soil amendments, etc (3)
- Farms under DIRECT MARKETING MODIFIED REQ: all of the above + must label all food at point of sale; also subject to withdrawal measures (3)

What are FULL REQUIREMENTS?

- Fully covered farms must comply with ALL Produce Rule measures: recordkeeping; worker health, hygiene, and training; soil amendments; certain water testing measures; wild and domesticated animals; buildings and equipment (4)
- SMALL BUSINESSES: 3 years to comply; 5 years for water testing (4)
- VERY SMALL BUSINESSES: 4 years to comply; 6 years for water testing (4)
- ALL OTHER BUSINESSES: 2 years to comply; 4 years for water testing (4)

1) What is a "qualified end user"? Either an individual (in any location) or a retail food establishment located in-state or within 275 miles. More details: <http://bit.ly/nsacproduce>
 2) Direct Marketing Modified Requirements are also known as the Tester-Hogan Exemption.
 3) Details on recordkeeping, enforcement, direct market labeling, and all levels of compliance: bit.ly/nsacproduce
 4) Details on requirements and compliance timeframes: <http://bit.ly/fsmapr1>

Qualified Exemption Review *Template*

Name and address of farm: _____

Date: _____

Sales receipts or records reflecting **total food** sales over the previous 3 years:

Year 1 (Sales year: _____) \$ _____

Year 2 (Sales year: _____) \$ _____

Year 3 (Sales year: _____) \$ _____

Average total food sales \$ _____

Average food sales to qualified end users (E.g. consumers, or grocery stores and restaurants within 275 miles or within the same state or Indian reservation) \$ _____

\$ _____ ÷ \$ _____ x 100 = _____ %

Average food
sales to qualified
end users

Average total
food sales

**Percent sales
to qualified
end users**

TEST YOUR WATER

Like a cholesterol test! Don't need to comply with this part of FSMA for several years, but get a sense of your risk

- Indicator: Generic E. coli (not total coliforms, not specific pathogens)
- High to low risk
 - surface → ground → municipal
 - overhead → drip
- Quality criteria
 - Pre-harvest: **below 126 CFU/100 ml**
 - Post-harvest: potable, **0 (no detectable) CFU/100 ml**
- Several test methods – see handout or:
<https://www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM575255.pdf>

SOPS FOR ROUTINE PROCESSES

- Set agreed upon standards
- For tasks that are complex or involve many steps that should be done in order, or where amounts must be accurate
- Useful where there is high worker turnover and a frequent need for retraining
- Help track mistakes and improvements

EXAMPLES:

- Leafy greens washing, drying and packing
- Tote washing and sanitizing
- Monitoring and changing sanitizers in wash water
- Moving animals



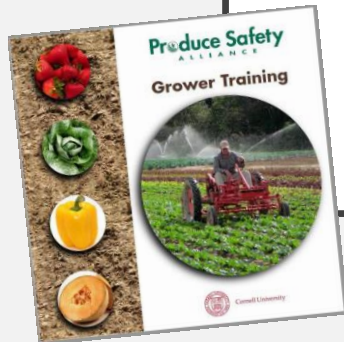
Standard Operating Procedures (SOPs)

- **A written document defining how to complete a specific food safety practice.**
- **SOPs include:**
 1. Step-by-step instructions to ensure that even a person who has never done a practice before can complete the practice correctly by following the instructions
 2. Location and name of any supplies needed to complete the practice
 3. When and how often the practice should be completed
 4. What records are needed/necessary

TRAIN YOUR EMPLOYEES

FSMA: §112.21(a-d)

- Farm personnel must be adequately trained upon hire and at least once annually
- Farm personnel must have adequate training and/or experience for their positions
- Training must be done so that it is understood (eg, in native language)
- Must be repeated if personnel fail to meet requirements
- Must be documented and include names of those trained, date and topics covered—signed by employee and supervisor/trainer



TRAIN YOUR EMPLOYEES

TRAINING MUST INCLUDE:

- Principles of food hygiene and food safety
- Recognizing symptoms of foodborne illness and the importance of personal hygiene for all personnel and visitors
- Other training relevant to the worker's job

AND MUST:

- Be appropriate for the job and conducted upon hiring
- Include refresher training throughout the season (at least annually) or when a problem arises
- Be easily understood
- Be supervised by a qualified person
- Include a process for documenting the training



CISA Winter Workshop: Developing Farm SOPs and Training Staff

February 9 @ 1:00 pm - 4:00 pm

In collaboration with MDAR and UMass we will go over how to create and implement Standard Operating Procedures (SOPs) and how to train your staff as it relates to Food Safety and the Produce Safety Rule under the Food Safety Modernization Act (FSMA). Gary Gemme of Harvest Farm of Whately will talk about some of his methods for staff training and management.

Location: Harvest Farm of Whately, 125 Long Plain Rd., South Deerfield

Presenters: Lisa McKeag – UMass Extension, Michael Botelho and Alexandra Hachem – MDAR, Gary Gemme – Harvest Farm of Whately

1. Attend a training
2. Figure out if you're covered
3. Participate in Commonwealth Quality
4. Test your water
5. Write SOPs for your routine processes
6. Train your employees on hygiene and farm practices
- 7. Assess risks**
- 8. Keep records**



Steps Towards Produce Safety

1

- Assess Produce Safety Risks

2

- Implement Practices

3

- Monitor Practices

4

- Use Corrective Actions

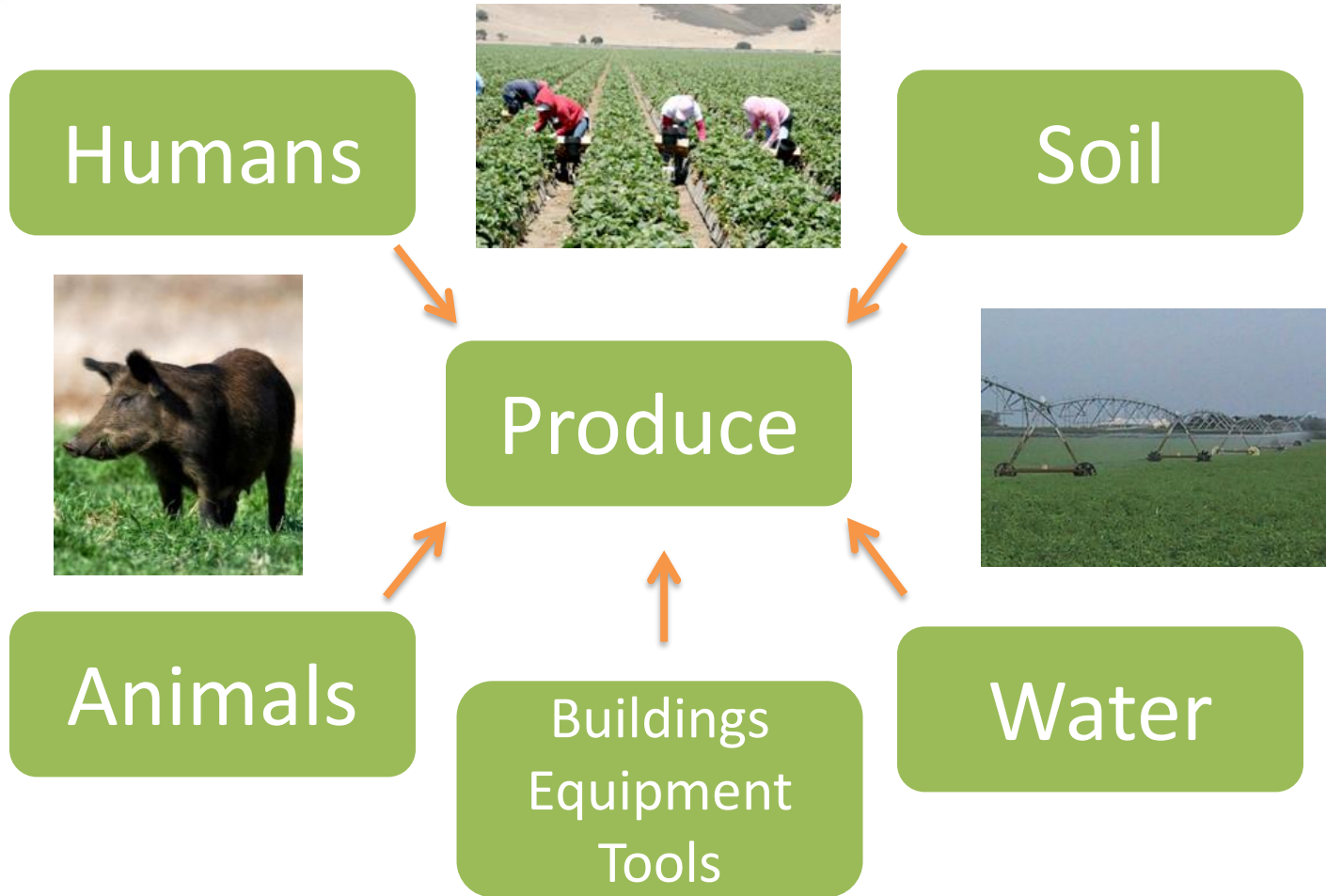
5

- Keep Records





Contamination Sources





Assessing Risks



- **Assess your farm and practices**
 - Location of farm, fields, and adjacent land activities that may represent risks to the crops you grow
 - Fecal contamination risk from domesticated or wild animals
 - Use of water and manure in crop production
 - Worker training programs and hygiene facilities
 - Practices used to grow, harvest, pack, or hold produce and the tools and equipment
 - Typical and atypical (e.g., flooding) situations



Implementing Practices to Reduce Risks



- Focus on preventing contamination
 - Cannot reliably remove contamination
- Address risks most likely to have the biggest impact on produce safety first
- May require modification of current practices and additional training for farm employees
- May require capital investment
- You may already be doing the right thing!
- Ask for help and seek training if you are unsure

ASSESSING RISKS

Anticipating guidance from FDA, MDAR on specifics, BUT...

A lot of decisions are going to come down to your judgements of what “adequate” means. What is your comfort level? Would you eat it? Do you feel comfortable putting it into the market place with your name on it? How would you respond in the case of an outbreak/issue? Where would you look first? What are *your* red flags?

- Learn the language
- Keep things clean and organized
- Know your policies and make sure your employees know them too (Farm plan a good idea).



**KEEP
CALM
AND
KEEP
RECORDS**

RECORDKEEPING

Recordkeeping is the big difference between being covered by the law and being exempt.

So, what records does FSMA require you to keep if you're fully covered?

If you're exempt?

Qualified exempt?

Should you keep records even if you're not fully covered? Yes!

RECORDS REQUIRED BY FSMA

- Records to Support a Farm's Coverage or Exemption Status
- Personnel Qualifications and Training (Subpart C)
- Agricultural Water (Subpart E)
- Biological Soil Amendments of Animal Origin (Subpart F)
- Equipment, Tools, Buildings, and Sanitation (Subpart L)

Required records must include:

- Name and location of farm
- Actual values and observations obtained during monitoring
- Adequate description of covered produce, if applicable to the record (e.g. commodity)
- Location of a growing area or other area, if applicable
- Date and time of the activity documented

REQUIREMENTS FOR QUALIFIED EXEMPT PRODUCERS

- Disclose the name and the complete business address of the farm where the produce was grown
- Maintain “adequate records necessary to demonstrate that your farm satisfies the criteria for a qualified exemption, including a written record that you have performed an annual review and verification of your farm’s continued eligibility for the qualified exemption.”

MAKE RECORDKEEPING WORK FOR YOU

- Build it into normal routines
- Helps you verify practices, identify trends or outliers, prevent problems



FOR ORGANIC PRODUCERS: RECORDS

Already used to keeping records, verifying inputs

Do not need to duplicate records

- Total gross sales, dollar amounts
- Buildings, Equipment, Tools and Sanitation
 - Buildings marked on farm map
 - Cleaning logs
- Water (need to do more testing than for NOP)
- Worker training – need to document
- NOP: tracking amount of harvested product.
FSMA has not issued requirements for traceability yet, but should have one step back/forward records

FOR ORGANIC PRODUCERS: INPUTS

- Manure is OK! No time interval in rule YET. Use NOP standard for now. (90/120 days)
- Manure, livestock, working animals, all OK—just change your risk assessment.
- FSMA does not discourage biological diversity and discourages the destruction of animals or animal habitat.
- Sanitizers? Don't need to use per FSMA. Make sure anything you use is OK by Org certifier.

SOME HELPFUL CONCEPTS

- Keep the poop off the food.
- Wash your hands, wash your hands again
- Consider and manage flow
- Manage pests
- Use smooth, cleanable surfaces in packing houses and pay attention to drains and standing water
- Keep things dry
- Make your tools work for you
keep things organized
use color coding, distinguish b/w harvest/storage/distribution
- Support a culture of food safety among employees

HANDWASHING

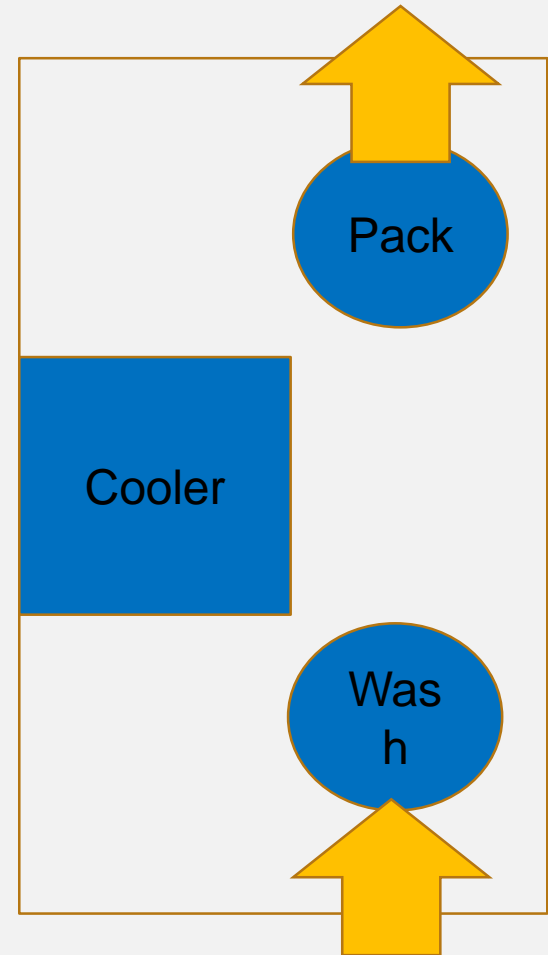
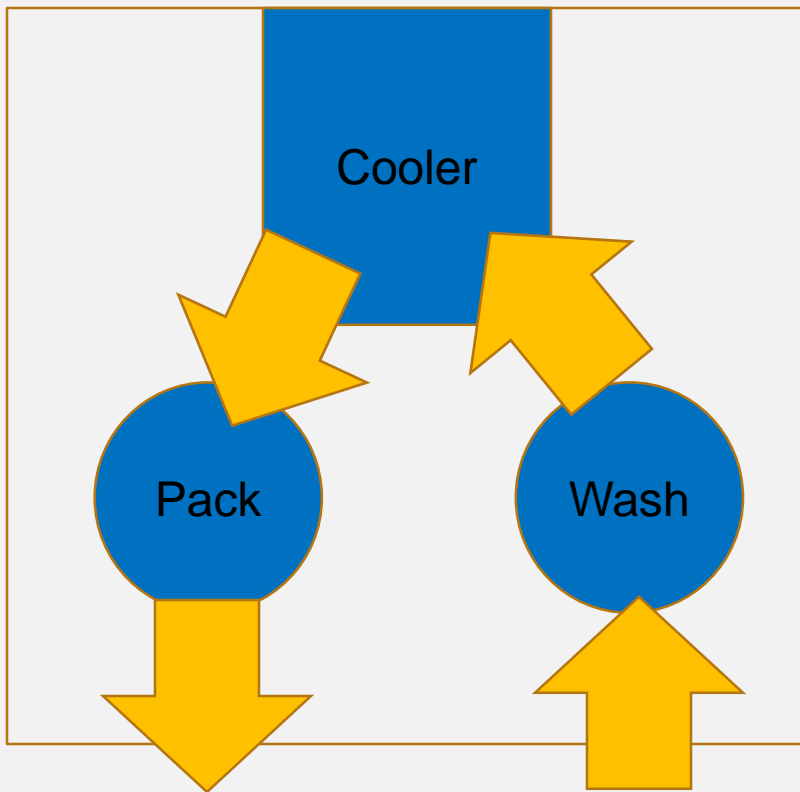
1. **Wet hands** with water
2. **Apply soap and lather.**
Be sure to wash the front and backs of hands as well as in between the fingers. Rub hands together for **AT LEAST 20 seconds**
3. **Rinse** hands thoroughly with clean water
4. **Dry** with a paper towel (turn off faucet with used towel)
5. **Throw** the paper towel in a trash can



FLOW OF PEOPLE / WORK HEALTH AND HYGIENE

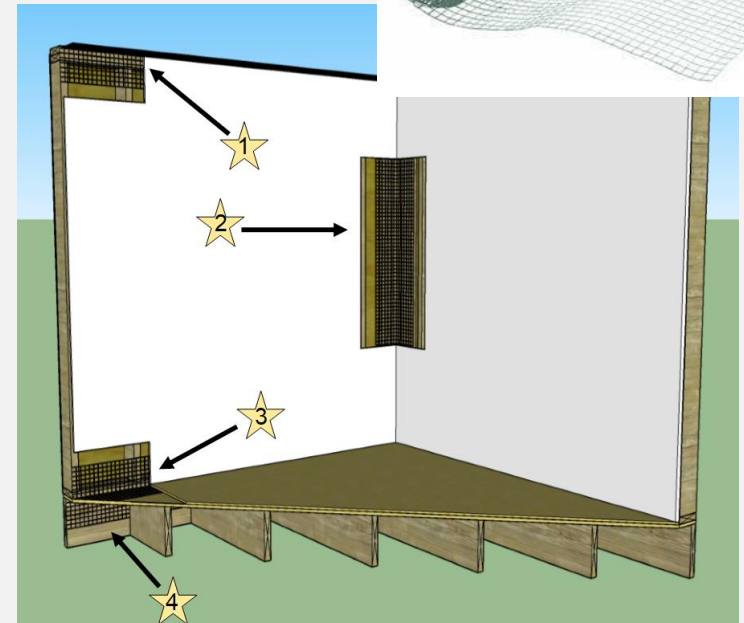
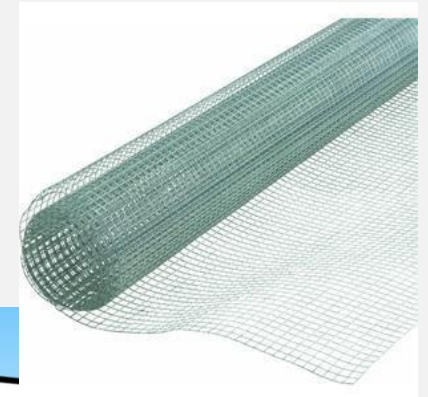
- Differentiate crews by task – harvest vs. wash/pack
- Or think about “clean breaks” between tasks
 - Wash hands, change boots, etc.
- Handwashing Sink
- Bathroom / Portalets

FLOW OF PRODUCT



RODENT & PEST CONTROL

- Remove Food
 - e.g., cull piles
- Limit Access
 - Tight construction
 - Flashing / wire mesh / hardware cloth at corners
 - Closed containers
 - Cement curbs
- Reduce Population
 - Bait, trap, kill



SMOOTH AND CLEANABLE MATERIALS



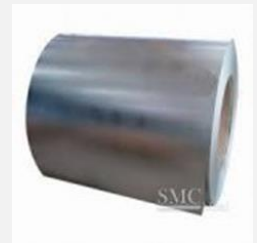
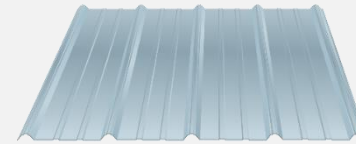
Fiber Reinforced Plastic
(FRP) aka "Dairyboard"
\$1.03-1.92 / ft²



WallTuf
\$1.25 / ft²



Galvanized Aluminum
(Galvalum)
\$0.76-0.95 / ft²



TrussCore
\$1.52 / ft²



Extrutech
\$2.20 / ft²



Utilite
\$1.85 / ft²



Ribcore
\$0.77 / ft²

DRYING

- After cleaning and sanitizing
- Allow time to completely dry
- Air movement
- Add some heat



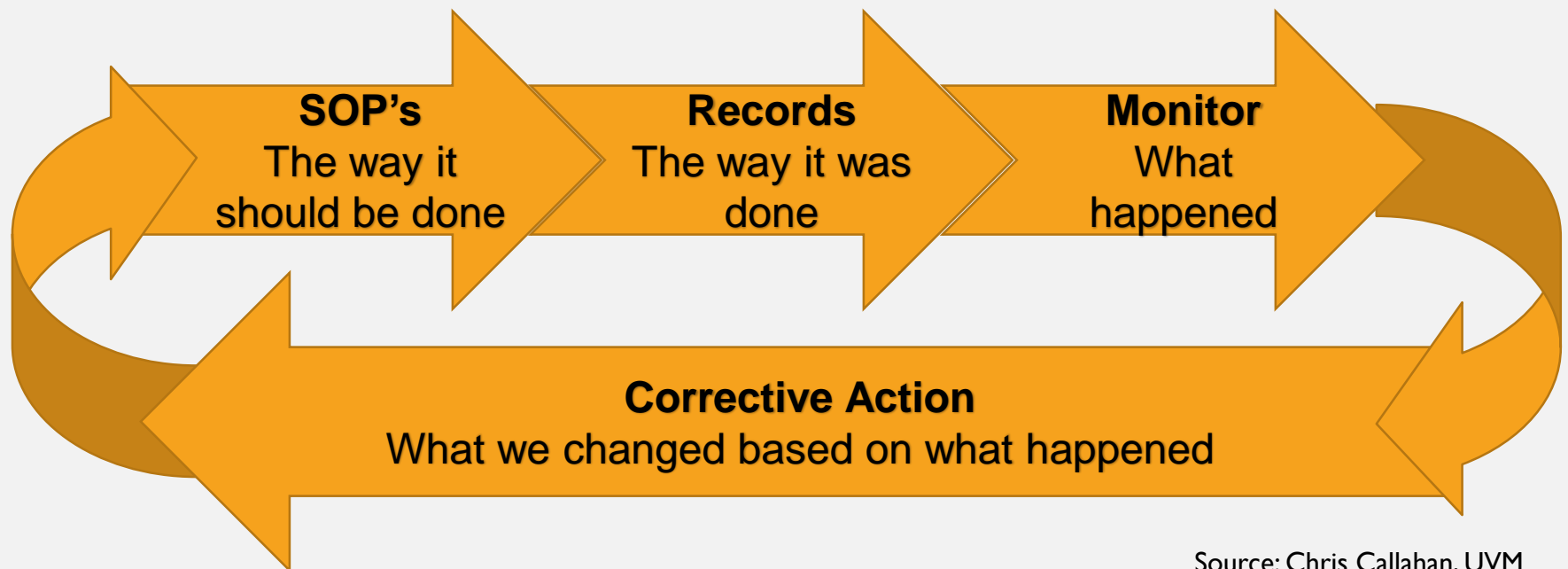
TOOLS AND CONTAINERS

- Keep things organized
- Use color, visual aids
- Smooth and cleanable
- Designated – harvest vs. storage vs. distribution?



CULTURE / SOP'S / RECORDS

- “The measured variable improves.”
- If you measure, record and review as a team, you will discover opportunities for improvement.



RESOURCES

- UMass
<https://ag.umass.edu/resources/food-safety/food-safety-for-farmers>
- MDAR
- Produce Safety Alliance
<https://producesafetyalliance.cornell.edu/>
- Produce Safety Network
<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM560008.pdf>
- Northeast Center to Advance Food Safety
<https://www.uvm.edu/extension/necafs>
- Local organizations: Berkshire Grown, CISA, NOFA/Mass, New Entry, SEMAP, Cape Cod Cooperative Extension, Sustainable Nantucket
- MDAR Grants – CISA, The Carrot Project provide grant writing help

THANKS!

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