

The Food Safety Modernization Act: What to Expect in Massachusetts

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The Center for
Agriculture,
Food and the
Environment



Who are we?

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<http://thecqp.com>

Who are you?

Overview

- The WHY: Food Safety is Important
- The WHAT: FSMA basics
 - Definitions
 - Major provisions
 - Compliance timeline
- State implementation and CQP
- Resources (the HOW??) and Questions

Food Safety is Important

- Fresh produce is the cause of most foodborne illnesses in the U.S.--the Center for Science in the Public Interest (CSPI)
- Pritzker Hageman Wins \$7.55 Million Verdict for Child with HUS E. coli -**not produce-related*

“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 are not generally implicated in foodborne illness outbreaks, BUT there is evidence that many cases of foodborne illness go unreported, and estimates of actual numbers are much higher than the official count



MASSACHUSETTS
Farm to School
PROJECT

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

FARM to INSTITUTION
NEW ENGLAND

Growing population of &
increased access to vulnerable
populations



Food Safety is Important

- Many MA growers will be technically exempt from FSMA Produce Rule
- Voluntary audits (e.g., USDA-GAP) buyer-driven, trainings not reaching small growers
- While FSMA sets minimum standards for larger producers, consumers have an expectation that these standards are being met by farms of all sizes.
- All growers will have to compete in the same market, to some extent
- Don't want to create a situation where some produce or some farms are perceived as being "cleaner" than others, because some have to comply with all of the requirements of the produce rule and some don't

The Food Safety Modernization Act (FSMA)

The Goals of FSMA:

- Reduce foodborne illness associated with the consumption of contaminated produce
- Set science-based minimum standards aimed at *preventing* rather than responding to foodborne illness outbreaks
- Give FDA authority to perform inspections

What necessitated FSMA?

- Increased # of outbreaks associated with fresh produce
- Several highly-publicized cases: Leafy greens, cantaloupe, peppers
- Increased consumption of fresh produce
- Outbreaks despite FDA guidance and voluntary audit programs
- Largest farms with long distribution chains considered greatest risk

7 rules in FSMA

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

The Produce Safety Rule

- **Food Safety Modernization Act, with Tester Amendment** was signed into law in January 2011
- **FDA issued proposed Produce Safety rule on Jan. 16, 2013**
 - Proposed standards for the growing, harvesting, packing, and holding of produce
 - Described FDA's thinking on specific issues related to:
 - coverage of rule,
 - water quality,
 - raw manure,
 - wildlife conservation, and
 - withdrawal of qualified exemption

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
- AKA **The Produce Safety Rule**

Standards for produce safety

- The Produce Safety Rule includes a set of standards that are deemed necessary to minimize MICROBIAL risks of fresh produce.

“Take appropriate measures to minimize the risk of significant adverse health consequences or death from the use of or exposure to covered produce—including those measures reasonably necessary to prevent introduction of known or reasonably foreseeable hazards and to provide reasonable assurances that produce is not adulterated.”

- The Rule sets the standards, tells the farmer WHAT must be done, but not necessarily HOW.
- Guidance documents are expected to help with this.

Where to find it:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>



FSMA Final Rule on Produce Safety

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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](#)



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.

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 Produce Safety Rule

The Produce Safety Rule has two parts, the **preamble** and the **codified sections**.

The preamble, includes FDA responses to public comments and provides the rationale as to why FDA made specific policy choices. [Preamble section may serve as guidance](#) until guidance documents are released.

The **codified sections** of the Produce Safety Rule can be found starting on page 74547 of the official Federal Register version. It ends on 74568. Read this section first.

Then, if you have questions about how the FDA came to its conclusions regarding a particular part of the rule, you can search the preamble using key words or codified section number to find discussion in the preamble pertaining to specific provisions.

SUBPARTS

A – General Provisions
B – General Requirements
C – Personnel Qualification & Training
D – Health & Hygiene
E – Agricultural Water
F – Biological Soil Amendments of Animal Origin and Human Waste
G – Reserved
H – Reserved
I – Domesticated and Wild Animals

J – Reserved
K – Growing, Harvesting, Packing, and Holding Activities
L – Equipment, Tools, Buildings and Sanitation
M – Sprouts
N – Analytical Methods
O – Records
P – Variances
Q – Compliance & Enforcement
R – Withdrawal of Qualified Exemptions

Definitions

The Produce Rule applies to *covered farms* doing *covered activities* on *covered produce*.

- Each of these terms has a specific definition in the Produce Rule.
- Therefore, if what you are doing on your farm does not fit these terms, then you are likely not subject to the rule. (*i.e. you do not fit the definition of *covered farm*, you do not conduct *covered activities* or grow *covered produce**)

Definitions: Covered Farm

- A *covered farm* is one that annually grosses *more than* \$25,000 in sales of produce, averaged across a rolling three-year period, and **adjusted for inflation** (with 2011 as the baseline year).
- <http://data.bls.gov/cgi-bin/cpicalc.pl>
(Inflation calculator)

Definitions: Covered Activities

- A *covered activity* means growing, harvesting, packing, or holding covered produce on a farm.

Definition: covered produce

- Produce means any fruit or vegetable, and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs.
- Covered produce means produce that is subject to these rules; so, produce that is in its **unprocessed** state, and is usually consumed **raw**.

Definitions: food

- *Food* means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes seeds and beans used to grow sprouts.
- (f) The term “**food**” means
 - (1) articles used for food or drink for humans or other animals,
 - (2) chewing gum, and
 - (3) articles used for components of any such article.

Definitions: very small farms

- Very small businesses, those with more than \$25,000 but no more than \$250,000 in average annual produce sales during the previous three year period

Definitions: small farms

- Small businesses, those with more than \$250,000 but no more than \$500,000 in average annual produce sales during the previous three year period

Not covered by the rule

- Farms that have an average annual value of produce sold during the previous three-year period of \$25,000 or less (*the de minimus exemption*) are *not covered by the rule*.
- Produce that is used for personal or on-farm consumption are *not covered by the rule*.

Not covered by the rule

- Produce that is not generally eaten raw and described as such in the rule is **NOT COVERED**
- 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; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts.

Not covered by the rule

- Produce does *not* include food grains
- Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (*e.g.*, cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

Exemption for processed produce

- The rule provides an exemption for produce that receives **commercial processing** that adequately reduces the presence of microorganisms of public health significance, under certain conditions.
- Need to show records that produce is bound for processing

Qualified Exemption

- To be eligible for a qualified exemption, the farm must meet two requirements:
 1. The farm must have **food (*not only produce*)** sales averaging less than \$500,000 per year during the previous three years; and

Qualified Exemption

2. The farm's sales to **qualified end-users** must exceed sales to all others combined during the previous three years.

A **qualified end-user** is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same state or the same Indian reservation as the farm or not more than 275 miles away.

Qualified exemption: modified requirements

- A farm with the qualified exemption must still meet **certain modified requirements**:
 1. disclosing the name and the complete business address of the farm where the produce was grown either on the label of the produce or at the point of purchase.

Subpart A – General Provisions

Subpart O – Records

Subpart Q – Compliance and Enforcement

Subpart R – Withdrawal of Qualified Exemption

qualified exemption: modified Requirements

2. Record-keeping requirements

- (a) You must establish and keep records required including sales receipts kept in the normal course of business. Such receipts must be dated.
- (b) You must establish and keep adequate records necessary to demonstrate that your farm satisfies the criteria for a qualified exemption, including a written record reflecting that you have performed an annual review and verification of your farm's continued eligibility for the qualified exemption.

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.

Reinstatement of exemptions

- A withdrawn exemption may be reinstated if (as applicable):
 - The FDA determines that the outbreak was not directly linked to the farm, and/or
 - The FDA determines that the problems with conduct or conditions material to the safety of the food produced or harvested at the farm have been adequately resolved, and continued withdrawal of the exemption is not necessary to protect public health or prevent or mitigate an outbreak of foodborne illness.

Compliance dates

Compliance dates for covered activities, except for those involving sprouts, after the effective date (**January 1, 2016**) of the final rule are:

- **Very small businesses**, those with more than \$25,000 but no more than \$250,000 in average annual produce sales during the previous three year period : four years = **January 1, 2020**

Compliance dates, Cont.

- Small businesses, those with more than \$250,000 but no more than \$500,000 in average annual produce sales during the previous three year period: three years = January 1, 2019
- All other farms: two years = January 1, 2018
- The compliance dates for certain aspects of the water quality standards, and related testing and recordkeeping provisions, allow an additional two years beyond each of these compliance dates for the rest of the final rule

Compliance dates cont.

Compliance dates for modified requirements for farms eligible for a qualified exemption are:

- For labeling requirement (if applicable): January 1, 2020
- For retention of records supporting eligibility for a qualified exemption: Effective date of the final rule (**NOW**)
- For all other modified requirements:
 - Very small businesses, four years after the effective date of the final rule
 - Small businesses, three years after the effective date of the final rule

Compliance dates cont.

Compliance dates for covered activities involving **sprouts** after the effective date of the final rule are:

- **Very small businesses:** three years
- **Small businesses:** two years
- **All other farms:** one year
- <http://www.pma.com/~/media/pma-files/food-safety/fsma/pma-reference-sheet-and-chart-for-fsma-compliance.pdf?la=en>

Standards for produce safety: personnel

Qualifications and training for personnel how handle covered produce or food contact surfaces (subpart C)

- Training for all personnel (and those involved in the supervision thereof), including temporary, part time, seasonal or contracted, ***adequate and appropriate to duties***, when hired and periodically after, ***at least yearly***
 - Records must be kept
- At least one supervisor or other responsible person must complete training at least equivalent to the standardized curriculum recognized by FDA (**Produce Safety Alliance training**).
- ***At least one person must be assigned responsibility to ensure compliance with the rule.***

Standards for produce safety: personnel

Health and Hygiene (subpart D)

Pathogens may be transmitted from workers to food

- Must prevent **ill or infected persons** from contaminating produce (communicable illnesses that present a risk, infection, open lesion, vomiting, diarrhea).
 - **Exclude** any person from working if they have an applicable health condition
 - Instruct personnel to **tell supervisor** if they have or if there is a reasonable possibility that they have these health conditions.

Standards for produce safety: Personnel

■ Hygienic practices

- Personal cleanliness
- Avoid contact with animals
- Washing hands, using gloves when appropriate
- Removing hand jewelry
- Not eating, chewing gum, using tobacco products in area used for covered activity

Standards for produce safety: personnel

- Make visitors aware of the same procedures
- Provide visitors with toilet and handwashing facilities

Standards for produce safety: agricultural water

Subpart E - Addresses water quality standards, inspection, maintenance, and testing requirements for water used in:

- Production
- Harvest
- Post-harvest handling

“All agricultural water must be safe and of adequate sanitary quality for its intended use”

Standards for produce safety: agricultural water

Some more definitions:

- **Agricultural water:** water used in **covered** activities on **covered produce** where water is **intended to or likely to contact** covered produce or food contact surfaces, including water used in growing activities
- Direct water application could include overhead irrigation of tomatoes, but probably not drip irrigation of tomatoes (but maybe drip for carrots)

Standards for produce safety: agricultural water

Inspection and maintenance of water distribution system

- At *beginning of growing season or at least once annually*, inspect entire ag water system
 - Water sources
 - Distribution systems
 - Facilities
 - Equipment
- Identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces.

Standards for produce safety: agricultural water

You will need to consider:

- The nature of each ag water source
- The extent of your control over it
- The degree of protection each source has
- Adjacent and nearby land use that may impact your water quality and
- The likelihood of introduction of hazards by another upstream use

You must adequately maintain all water sources, *to the extent they are under your control*; your distribution system *to the extent it is under your control*; and your water system to reduce potential for covered produce to contact pooled water.

Standards for produce safety: agricultural water

Microbial Water Quality Criteria

For water used to irrigate sprouts, or to directly apply to produce during harvest or post-harvest; for food contact surfaces; or in hand-washing, the standard is **no detectable generic *E. Coli* per 100mL = potable water**

For water used **during growing activities**, when used in a manner that is *intended or likely to contact produce*, the standard is:

- A geometric mean (GM) of your ag water samples of 126 or less colony forming units (CFU) of generic *E. coli* per 100mL of water and
- A statistical threshold value (STV) of your ag water samples of 410 or less CFU of generic *E. Coli* per 100mL of water

Standards for produce safety: agricultural water

Water used during **harvest, packing, holding** activities

- Manage water to maintain its safety and adequate sanitary quality, minimize chance of contamination
 - Address **water change schedules** for re-circulated water
 - **Visually monitor** quality of water for build up of organic material
 - Maintain and **monitor temperature** of wash water appropriate to commodity

Standards for produce safety: agricultural water

Records

- Water system inspection findings
- Documentation of test results
- Documentation of results of water treatment monitoring
- Scientific data supporting water treatment method, if using and documentation of how you determine that produce is safe if water used exceeds standards (using die off or post-harvest treatment to address this)

Standards for produce safety: Biological Soil Amendments of Animal Origin

Holding, transporting, storing, treating, applying biological soil amendments of animal origin (BSAs), including agricultural teas (Subpart F)

- Standards for **treated** BSAs
 - Processed to completion to adequately reduce microorganisms of public health significance
 - Untreated surface water cannot be used to make ag teas
 - Process must be validated to satisfy microbial standards for *Listeria monocytogenes*, *Salmonella*, and *E. Coli* O157:H7 or *Salmonella* and fecal coliforms

Standards for produce safety: Biological Soil Amendments of Animal Origin

- **How to handle, convey, store soil amendments of animal origin**
 - (untreated) So as not to become a potential source of contamination to covered produce, food contact surfaces, areas used for covered activity, water sources, water distribution systems and other soil amendments
 - (treated) so as not to contaminate the treated amendment

Standards for produce safety: Biological Soil Amendments of Animal Origin

Records to keep

- Records that document treatment process—whether you did it or if you bought it treated.
- In addition, whether purchased or if you composted/treated it, you need documentation that once purchased it was handled, conveyed and stored in a manner and location to minimize risk of contamination by untreated or in process waste.
- If you follow either the static process or turned process, then you only need to document that you are following process controls (time, temperature, turning, curing), you do not need to test.

Standards for produce safety: domesticated and wild animals

Subpart I: standards for minimizing food safety risks associated with wild or domesticated animals.

- Applies to growing, harvesting, packing, holding when done in an outdoor area or partially enclosed setting and there is a reasonable probability that animals will contaminate covered produce—does not apply to fully enclosed buildings
- You will need to:
 - Assess the areas used for covered activities for evidence of potential contamination as needed during growing season.
 - If evidence of potential contamination is found, evaluate whether the produce can be harvested; if likely to be contaminated, then identify/mark the produce area so that this produce will not be harvested.

Standards for produce safety: domesticated and wild animals

Pets/domestic animals

- If they are in or around fully enclosed buildings, then you must take precautions to prevent contamination
- Excluding from buildings where covered produce, food contact surfaces or food packing material is exposed or
- By separating them by time, location, or partition

Standards for produce safety:

growing, harvesting, packing and holding activities

Subpart K: Growing, harvesting, packing, holding

- Identify and do not harvest produce reasonably likely to be contaminated—at minimum—**e.g., you can see poop**
- Keep covered produce away from excluded produce (unless for distribution)
- Adequately clean food contact surfaces after excluded produce has been used on it, before using the surface for covered produce

Standards for produce safety:

growing, harvesting, packing and holding activities

Subpart K: Growing, harvesting, packing, holding, continued

- Handle covered produce so it does not become contaminated
- Do not distribute dropped produce
- Packaging
 - In a manner that does not allow growth of *C. Botulinum*
 - Use cleanable packaging or designated for single use; unlikely to support growth of bacteria, etc.

Standards for produce safety: Equipment/tools/buildings/sanitation

Subpart L: equipment, tools, buildings (see GMPs)

- Requires tools and equipment to be:
 - Designed, installed, stored to allow for adequate cleaning and maintenance
 - Inspected, maintained, and cleaned when appropriate and *as frequent as necessary* to protect from contamination
- Buildings
 - Suitable in size, construction, and design to facilitate maintenance and sanitary operations; sufficient space for storage; separation of operations that introduce the potential for contamination by location, time, partition, etc.

Standards for produce safety: Equipment/tools/buildings/sanitation

Other standards relating to:

- Pest control
- Domestic animals in enclosed buildings
- Toilets and handwashing facilities
- Sewage and waste disposal
- Plumbing
- Domesticated animal litter, records—especially related to date and method of cleaning and sanitizing equipment

Record keeping

- **General requirements for all records**
 - Name and location of farm
 - Actual values and observations obtained during monitoring
 - Adequate description of relevant covered produce, commodity name, lot number or other identifier

Record keeping

- **General requirements for all records**
 - Location of the growing area post-harvest area
 - Date and time of activity documented
 - Created at time of activity is performed or observed
 - Be accurate and legible
 - Dated and signed by person who conducted the activity

What to do now?



What to do now?

DON'T PANIC—we have time to figure this out and, there are things you can do now to get moving on the right track

Look at your records

Go back 3 years if possible

Can you show:

- Total sales figures
- Food vs. Non-food sales
- Sales to qualified end users vs. all others

FSMA enforcement

- Will be enforced by states
 - Department of Agriculture (most states, including MA)
 - Department of Public Health
- Cooperative Agreement with FDA to support education, outreach, technical assistance and inspection and enforcement
- Use existing authorities, existing resources

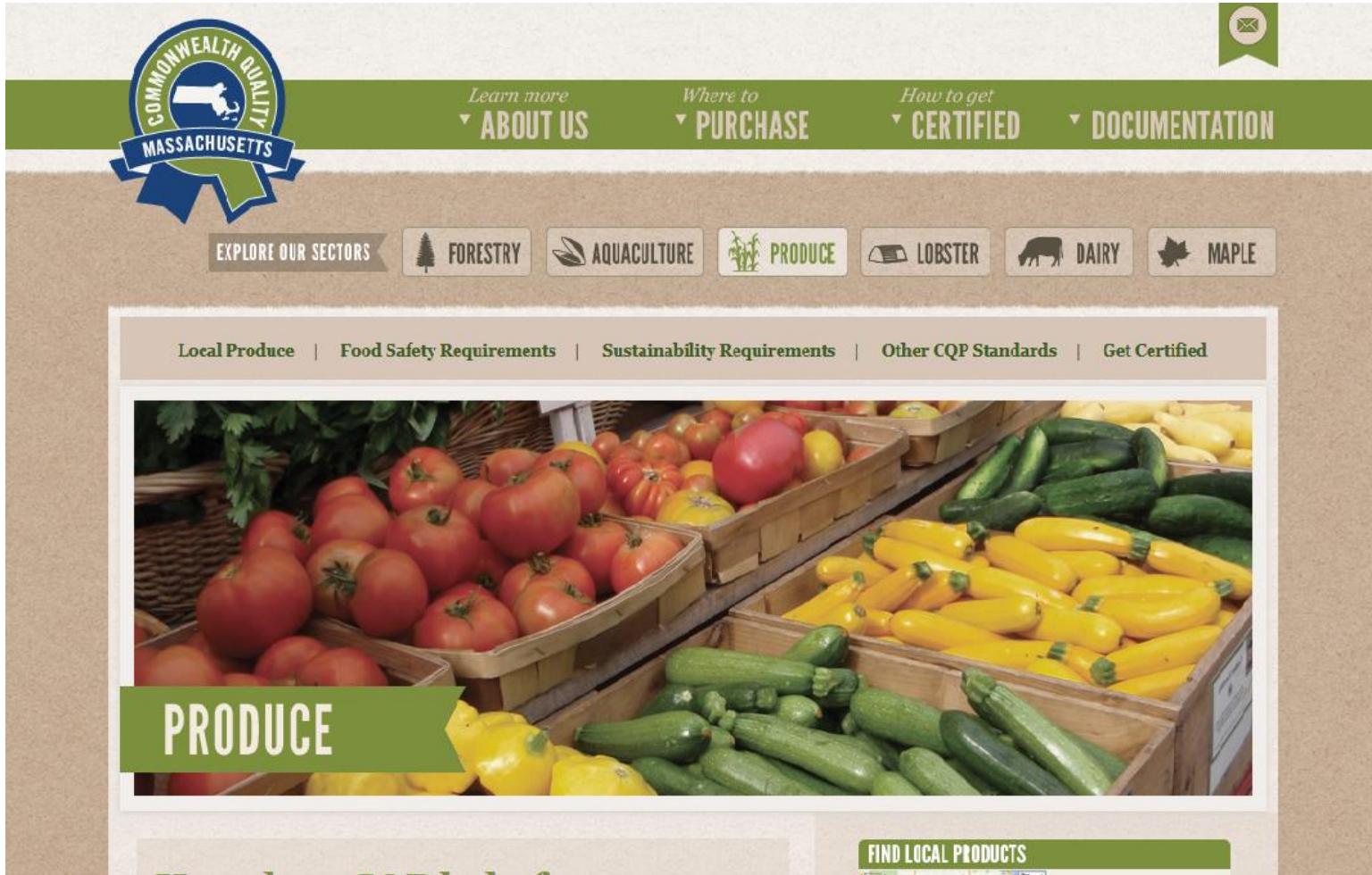
How will this play out in MA?



- We have an advantage over other states, ready-made tool



<http://theCQP.com>



The screenshot shows the homepage of theCQP.com. At the top left is the Commonwealth Quality Massachusetts logo, which includes a map of Massachusetts and the text "COMMONWEALTH QUALITY MASSACHUSETTS". To the right are four main navigation links: "Learn more ABOUT US", "Where to PURCHASE", "How to get CERTIFIED", and "DOCUMENTATION". Below these are five smaller links under the heading "EXPLORE OUR SECTORS": FORESTRY (with a tree icon), AQUACULTURE (with a fish icon), PRODUCE (with a stalk of vegetables icon), LOBSTER (with a lobster icon), DAIRY (with a cow icon), and MAPLE (with a maple leaf icon). A large image of various fresh produce like tomatoes, cucumbers, and yellow squash is centered below the navigation. Overlaid on this image is a green banner with the word "PRODUCE" in white. At the bottom right of the image is another green banner with the text "FIND LOCAL PRODUCTS". At the very bottom of the page is a thin horizontal bar containing several small, illegible icons.

Learn more **ABOUT US** Where to **PURCHASE** How to get **CERTIFIED** DOCUMENTATION

EXPLORE OUR SECTORS FORESTRY AQUACULTURE PRODUCE LOBSTER DAIRY MAPLE

Local Produce | Food Safety Requirements | Sustainability Requirements | Other CQP Standards | Get Certified

PRODUCE

FIND LOCAL PRODUCTS

What is CQP?

- 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
- AFSIP- Agricultural Food Safety Improvement Program
 - Participants reimbursed up to \$20,000 or 75% of their total project costs

Commonwealth Quality

- Developed on the premise that every Massachusetts farm would need support:
 - Independent of market.
 - Independent of size.
 - Independent of crop.
 - Key message for the go-local movement.
 - Market forces would be unleashed that would change local supply.



Commonwealth Quality

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



Commonwealth Quality

- Provide third party audit support:
 - Utilizing GAPS and industry BMPs.
 - Reduce paperwork (food safety plan)
 - Work with buyers for acceptance.
 - Use as a stepping stone to GAPs and FSMA.
- Manage change for the producer effectively and reduce pain!!



Commonwealth Quality

- Working with FDA on enforcement plan for FSMA

The HOW...

- FSOP, NOFA partner
- Training opportunities – PSA curriculum
- On farm workshops
- Research
- Regulatory updates, news on labs, water testing resources
- NECAFS – big web of communication

Thanks!

- Thanks to Diane Hirsch, UConn Extension for handouts and many FSMA slides
- And to YOU for coming!