

Delaware Cooperative Extension 2015 FSMA in Delaware

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FSMA Has Been Incorporated into DE Extension GAP/GHP Training Sessions

- Basic Session
 - Microbial Risks
 - Legal and Regulatory Issues (FSMA)
 - Good Agricultural Practices Basics
 - Good Handling Practices Basics
- Wholesale Session
 - Preparing for an Audit
 - Writing Your Produce Food Safety Plan
 - Farm
 - Packing House
 - Combined
 - Record Keeping



Delaware Cooperative Extension
2015 Produce Food Safety
GAP/GHP Updates

*FSMA has been incorporated since
2012 in update sessions*

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FDA Food Safety Modernization Act

Who is exempt, partially exempt, and who is covered

- >\$500,000 of produce - COVERED
- \$25,000 - \$500,000 and majority wholesale – COVERED
- \$25,000 - \$500,000 and mostly direct market – MODIFIED EXEMPTION
- \$25,000 or less of produce – EXEMPT
- Do not grow fresh consumed produce – NOT COVERED BY FSMA (i.e. sweet corn, potatoes)
- Grow processing vegetables – NOT COVERED IF NO DUAL USE (i.e. lima beans)
- Grow processing vegetables that might have dual end use (such as pickling cucumbers, spinach) UNCLEAR

Watermelons – GAP/GHP's, FSMA



Fresh Consumed Produce (like the Cabbage packed here) GAP/GHP's, FSMA



Sweet Corn – GAP/GHP's not FSMA



Potatoes - GAP/GHP's not FSMA



Local Wholesale FSMA, Buyer dependent GAP/GHP's



Issue – Produce Rules or Preventative Controls Rules Farm or Facility?



Packing location
Multiple farms packing
Produce treatments

Auctions – Specifics of how they are they covered under FSMA?



Farm Market – Retail FSMA still unclear, may have own rule



Farmers Market Vendors, CSA's – FSMA still unclear, may have own rule



Small On Farm Processing – FSMA Register but exempt from HARPC? *Already state regulated*

Do You Conduct Only “Low-Risk” Activities?

Farm mixed-type facilities that are small or very small businesses are eligible for an exemption from the Hazard Analysis and Risk-Based Preventive Controls (HARPC) requirements in the Preventive Controls Rule, if the only activities they conduct as part of their facility operation are ones that FDA considers to be “low risk.”

Example: Jams, Jellies

Good Agricultural Practices

Water Safety and FSMA

- Microbial contamination
 - Natural/wildlife
 - Farm animals/manure
 - Sewage/human
- Chemical contamination
 - Pesticides
 - Other chemicals
- How water contaminates produce
 - Irrigation
 - Wash water
 - Spray water
- Water Testing
- Water Treatment



Water Testing Changes

- Water sources must be tested
 - Irrigation, spray, wash, and drinking water
 - Drinking water standards for all but irrigation
- Schedule for testing
 - **Municipal water – acquire test results annually?**
 - **Well water – Once a year (Will change – proposed 4x)**
 - Beginning of season
 - **Surface water – Two times a year (Will change – proposed 20 sample baseline over 2 years)**
 - Beginning of season and near harvest

Standards For Irrigation Water

Currently – **Will change under FSMA**

– E. coli

- Geometric mean of 5 samples - <126 CFU/100 ml
with no sample over 235 CFU/100ml
- **Non foliar contact - <576 CFU/100 ml**

Water Testing Proposals

For farmers that have to test water, FDA is proposing three numerical standards for testing:

1. **No detectible *E. coli* present per 100 ml of water:** This standard would apply to water used for an activity during and after harvest, water used to make agricultural teas, and water used in sprout irrigation.
2. **A geometric mean of no more than 126 CFU per 100 ml:** This standard would apply to untreated groundwater used to irrigate in a manner that directly contacts the harvestable portion of the crop.
3. **A statistical threshold value of 410 colony forming units (CFUs) generic *E. coli* per 100 ml for a single water sample, and a geometric mean of no more than 126 CFU per 100 ml:** This standard would apply to untreated surface water used for growing activities (except for sprouts) that directly contact the harvestable portion of the crop. If your water testing shows that you exceed these values, you can still use your water, as long as you apply an appropriate time interval between the end of irrigation and harvest (see the “Calculating Microbial Die-off” section below).

This is a significant change from FDA’s original approach, which set a limit of 235 CFU per 100 mL and prohibited the use of water that exceeded this limit.

Well Water Baseline Testing

FDA's New Approach to Testing and Using Untreated Groundwater

If you are using untreated groundwater, FDA has proposed a tiered testing approach like that for untreated surface water:

1. **Conduct a baseline survey to develop a water quality profile:** FDA is proposing to require at least four tests during the growing season or over the period of one year, using at least four samples collected as close as practical to harvest.
 - If the groundwater is for post harvest use, handwashing, sprouts, agricultural teas, or it contacts food-contact surface, the standard is no detectable generic E. coli per 100 mL
 - If you are using the water for irrigation and it will directly contact the harvestable portion of the crop, the standard is a geometric mean of generic E. coli of 126 CFU or less per 100 mL
2. **Annual Verification:** If you meet the applicable standard in your baseline survey, then you only need to test once annually. But, you must resume testing at least four times per year (or growing season) if any annual test fails to meet the standard.

Surface Water Baseline Testing

FDA's New Approach to Testing and Using Untreated Surface Water

FDA has proposed a new tiered approach to testing and using untreated surface water that is directly applied to the harvestable portion of the crop:

- 1. Conduct a baseline survey to initially develop the water quality profile of each of your water sources:** FDA is proposing that you develop your water quality profile by calculating the geometric mean (GM) and the statistical threshold value (STV) of generic E. coli (in CFU per 100 mL) using at least 20 samples over at least two years. You should sample the water as it's used (e.g. at the end of the sprinkler), and collect the samples during a time period as close as practical to harvest.
 - If your water quality profile is above the STV and GM thresholds, then you are not required to stop using that water source. Instead, you can still use the water in conformance with the microbial die-off provision (see "Calculating Microbial Die-Off" below).
- 2. Verify your water quality profile through annual sampling:** Each year, you must take at least 5 new samples to verify the accuracy of your water quality profile. If your annual survey is sufficiently different from your existing water quality profile, then you would have to update your water quality profile and make adjustments to your practices.
- 3. Re-establish your baseline:** FDA is proposing that you re-establish your baseline survey every ten years, or sooner if your annual survey samples do not support your water quality profile, and then adjust your practices accordingly (e.g. wait another day or two before harvesting, based on the microbial die-off rate).

Die Off Provision

Calculating Microbial Die-Off

If you are using untreated surface water to irrigate in a way that directly contacts the harvestable portion of the crop, and your water quality exceeds the proposed STV and GM thresholds, you can still use that water as long as you wait enough time to account for the natural reduction in generic E. coli (“microbial die-off”) that would bring you below within the threshold. If this confuses you, you aren’t alone. This is a relatively complicated concept, and FDA recognizes that they will need to provide guidance and education to help farmers calculate the appropriate number of days that they need to wait between the end of irrigation and harvest.

FDA has proposed a die-off rate of 0.5 log per day that would apply to determine the number of days you must wait between irrigation and harvest. This rate means that every day after you irrigate, you can assume a roughly 67% reduction in generic E.coli on the surface of the crop due to natural causes like sunlight, moisture, temperature, pH, etc. **FDA provides some examples** of how applying the 0.5 log die-off rate allows you to use water that would otherwise exceed the standard.

Water Testing Compliance Dates

Compliance Dates

Because the agricultural water standard is based on limited scientific evidence, because there are huge research gaps in agricultural water issues, and because the proposed standards are untenable at this time, FDA is proposing extended compliance dates for the agricultural water standards.

For the water testing, monitoring, and associated recordkeeping requirements, FDA is proposing the following compliance dates from the time that the final Produce Rule goes into effect:

- Six years for very small businesses,
- Five years for small businesses, and
- Four years for all other farms.

Small and very small farms may find the costs of annual testing, and establishing the baseline survey in particular, to be quite burdensome. As a way to spread out the costs of compliance, small and very small farms have more time to come into compliance with the requirement. Spreading out the 20 samples required for a baseline across 4-6 years makes achieving the baseline less onerous. Allowing farmers to rely upon past year's data in establishing a new baseline will also help spread the costs of compliance. However, FDA is requesting comments on how long past year's test results should be viable to use in calculating the baseline. This means that they could decide that test results older than 3 years (for example) cannot be used.

Manure Use – What will be the Final Rule

2. Manure strategy to be further studied

- The FDA is removing the nine-month proposed minimum-time interval between the application of untreated biological soil amendments of animal origin (including raw manure) and crop harvesting. The agency is deferring its decision on an appropriate time interval until it pursues certain actions. These include conducting a risk assessment and extensive research to strengthen scientific support for any future proposal, working with the U.S. Department of Agriculture and other stakeholders.
- At this time, the FDA does not intend to take exception to farmers complying with the USDA's National Organic Program standards, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil.
- The FDA is proposing to eliminate the previously proposed 45-day minimum application interval for compost (also known as humus), including composted manures. Properly treated and handled compost is safer than raw manure from a public health standpoint and this change to the proposal would help facilitate its use while still providing an appropriate level of public health protection.

Additional Information

- [The Food Safety Law and the Rulemaking Process: Putting FSMA to Work](#)
- [FSMA 101 and Rulemaking 101](#) (video tutorials)
- [The Food Safety Law and the Rulemaking Process: Putting FSMA to Work](#)
- [Background on FSMA](#)

Withdrawal of Exemption

4. Withdrawal of qualified exemptions process further clarified

- The proposed revisions would establish procedures to guide the FDA in withdrawing an exemption for a farm for food safety reasons as specified in the proposed regulation:
 - The FDA may consider one or more other actions to protect public health prior to withdrawal, such as a warning letter, recall, administrative detention, or seizure and injunction.
 - The FDA must notify the farm of the circumstances that jeopardize the exemption, provide an opportunity for the farm to respond, and consider actions taken by the farm to address the issues raised by the agency.
- The revisions also provide procedures for reinstating a withdrawn exemption.

Educational Area VII. GAP and GHP Third Party Audits - Incorporating FSMA

- Educate about third party audit program
 - Why audits are needed
 - Wholesale buyers
 - Government buyers
 - Who does the audit
 - Private companies
 - USDA
 - What happens in an audit
 - Announced
 - unannounced
 - Keys to passing an audit




Produce GAPs Harmonized Food Safety Standard Field Operations & Harvesting - USDA Checklist

AUDITEE INFORMATION	
Company Name:	_____
Audited Location Address	GPS (Optional): _____
Street: _____	City, State, Zip: _____
Multiple sites covered by this audit? (If Yes, provide details in Additional Comments) <input type="checkbox"/> Yes <input type="checkbox"/> No	
Mailing/Business Address <input type="checkbox"/> Same as above	
Street: _____	City, State, Zip: _____
Company Contact: _____	Contact Title: _____
Phone Number: _____	Fax Number: _____
E-Mail Address: _____	
Company uses USDA GAP&GHP Logo on packaging or marketing materials? <input type="checkbox"/> Yes <input type="checkbox"/> No	
AUDIT INFORMATION	
Date and Time of Audit	Beginning Date: _____ Time: _____
	Ending Date: _____ Time: _____
Description of Operation:	_____
Harvest Company Name (if applicable):	_____
Other Contractors:	_____
Commodities Covered by Audit:	_____
Commodities Produced During Audit:	_____
Total Acres Covered by Audit:	_____
Send Certificate to: (choose) <input type="checkbox"/> Inspection Office (list office) _____	
	<input type="checkbox"/> Directly to auditee above
AUDITOR INFORMATION	
United States Department of Agriculture	Field Office: _____
Agricultural Marketing Service	
Fruit and Vegetable Programs	Auditor Name(s): _____
Specialty Crops Inspection Division	Auditor Signature(s): _____

Educational Area VII. GAP and GHP Third Party Audits – Adding FSMA Requirements

- Third party audit program
 - Why audits are needed
 - Wholesale buyers
 - Government buyers
 - Types of Audits
 - Who does the audit
 - Private companies
 - USDA
 - What happens in an audit
 - Announced
 - unannounced
 - Keys to passing an audit

USDA Good Agricultural Practices & Good Handling Practices
Audit Verification Checklist



This program is intended to assess a participant's efforts to minimize the risk of contamination of fresh fruits, vegetables, nuts and miscellaneous commodities by microbial pathogens based on the U.S. Food and Drug Administration's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables."

Firm Name: _____

Contact Person: _____

Audit Site(s): _____

Main Address: _____

State: _____ Zip: _____ Telephone No: _____

Fax: _____ E-mail: _____

Auditor(s): (list all auditors with the lead listed first) _____

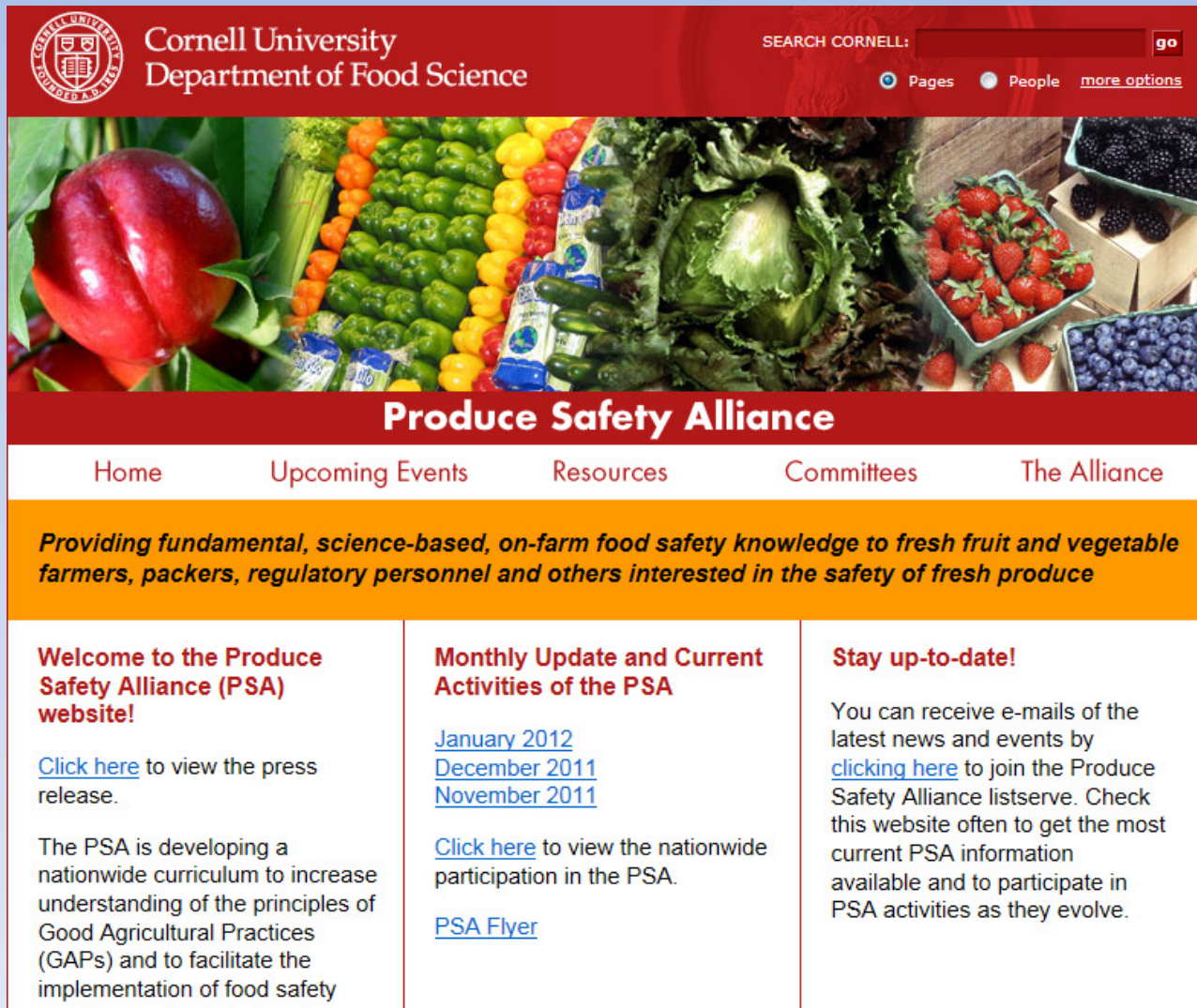
USDA or Fed-State Office performing audit: _____

Date & Time Arrived: _____ Date & Time Departed: _____

Travel Time: _____ Code: _____

Person(s) Interviewed: (use back of sheet if necessary to list all persons interviewed) _____


Training Requirements and FSMA?



Cornell University
Department of Food Science

SEARCH CORNELL: **go**

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Produce Safety Alliance

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Providing fundamental, science-based, on-farm food safety knowledge to fresh fruit and vegetable farmers, packers, regulatory personnel and others interested in the safety of fresh produce

<p>Welcome to the Produce Safety Alliance (PSA) website!</p> <p>Click here to view the press release.</p> <p>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</p>	<p>Monthly Update and Current Activities of the PSA</p> <p>January 2012 December 2011 November 2011</p> <p>Click here to view the nationwide participation in the PSA.</p> <p>PSA Flyer</p>	<p>Stay up-to-date!</p> <p>You can receive e-mails of the latest news and events by clicking here to join the Produce Safety Alliance listserv. Check this website often to get the most current PSA information available and to participate in PSA activities as they evolve.</p>
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