What is the Food Safety Modernization Act and How Can I Comment on It?

Acknowledging that due to a rise in major outbreaks of foodborne illness was focused mainly on the processing, manufacturing sectors – areas shown to be of highest risk for foodborne illness. In 2009 and 2010 Congress debated a number of food safety proposals that directly and indirectly affected farms and on-farm processing.

Recognizing the burden of food safety proposals that directly and indirectly affected farms and on-farm processing.

Recognizing that supporting the importance of food safety proposals that directly and indirectly affected farms and on-farm processing.

Rejecting a food safety proposal that focused on preventative controls rather than monitoring and remediation procedures.

Ensuring food safety is not as simple, however, as requiring all farms and facilities to meet appropriate federal regulation.

Where Did FSMA Come From?

Due to the actions of thousands of farmers and concerned consumers, however, the new food safety law that Congress passed and that President Obama signed included the following critical provisions:

• Scale-appropriate regulations: Rejecting a “one-size-fits-all” approach, FSMA includes options for small, mid-sized, and direct-market agricultural operations to comply with equivalent state regulations or modified, scale-appropriate federal regulations.

• Conservation practices: Recognizing that conservation practices have a number of public benefits, FSMA indicates that new regulations should not undermine beneficial on-farm conservation and wildlife practices.

• Organic production: Acknowledging that organic production and food safety go hand-in-hand, FSMA specifies that new regulations must complement – not contradict – strict regulations for certified organic production.

• Value-added processing: Supporting the development of new low-risk processing businesses, FSMA minimizes extra regulations for low-risk processing that is part of value-added production.

• Paperwork reduction: These proposals extended FDA regulatory authority to farms and made some on-farm safety standards mandatory. Concurrently, the Obama Administration created an inter-agency Food Safety Working Group through which the FDA and the U.S. Department of Agriculture started adopting new food safety standards and oversight responsibilities.

Due to the actions of thousands of farmers and concerned consumers, however, the new food safety law that Congress passed and that President Obama signed included the following critical provisions:

1. A chemical compound that is added to protect against decay or decomposition.
2. A food safety proposal that focuses on preventative controls rather than monitoring and remediation procedures.
3. Practicable, because they can cause travellers sickness.
4. Food additive used as a nutrient supplement; can also be used to purify water and as a disinfectant (NEVER carelessly).
5. Frequently implicated in Salmonella food poisoning cases.
6. Any of various fungi that often cause disfigurement of organic matter.
7. Salmonella enteritidis is a strain associated with this source.
8. Usually heated to 161°F (72°C) for 15 seconds during processing.
9. This space, one of the world’s oldest, has been shown to KHEE; call 01377 277 in recent studies. (Kansas State U. 1999)
10. Low acid canned foods such as this are most likely sources for inclusion.
11. Infectious problem before thought to be responsible for diseases like Spleen and SSG.
12. Any variety of fungi that often cause disfigurement of organic matter.
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by Jack Kittredge

This issue focuses on the proposed regulations that the U. S. Food and Drug Administration (FDA) released in January for public comment. The regs are designed to enforce the Food Safety Modernization Act (FSMA) passed by Congress and signed into law in January, 2011. Originally the comment period for these regs was to end on May 16, but widespread concerns, including that such a date caught farmers in the midst of the busy planting season, has persuaded the FDA to extend the comment period until September 16.

We hope that the information presented here helps you understand the concerns that the FDA has with the problem of microbial contamination of food in this country. According to the FDA itself, despite the US claiming to have the safest food supply in the world, about 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases (Center for Disease Control estimates as of Feb. 6, 2013). So it is not as safe as it might be!

Many changes will be required of farmers in the months and years to come because of these regulations, so it is important that you understand them. But it is also important at this time that you not only understand them, but make the effort to contact the FDA with your comments this summer, before they become final.

When the USDA regulations governing the National Organic Program were first presented to the public in the winter of 1997-98, opposition to them was so widespread (they allowed Irradiation, GMOs and sewage sludge in organic, among other things) that the USDA revoked them and issued entirely new ones after four more years of study. So it is possible to affect this process if public concerns are widespread and presented to the FDA. How to do this is well documented in this issue.

But many observers wonder whether the concern of our government for food safety is not myopic. We are witnessing a gargantuan effort to keep pathogens out of our food. Yet when it comes to other -- far more sinister -- problems with food safety the FDA has been almost criminally negligent.

The agency has, for example, for almost 20 years allowed the widespread adulteration of food with new and untested proteins stemming from transgenic crops. This was done to increase the competitive advantages of American business, despite numerous warnings about the untested products being unsafe for the food supply.

When first presented with GMOs, FDA’s scientists howled and fired off memo after memo declaring that transgenics presented serious potential human health risks. But they were ignored. The result, two decades later, may well be a national epidemic of inflammatory and auto-immune diseases.

I say “may well” because the FDA has required no testing of these foods, and they go unlabeled in the food supply, so no one can know for sure how much of them we are eating or what damage they are doing.

Another example of FDA’s myopia is the specific allowance in these FSMA regulations of the use of sewage sludge as fertilizer. Study after study has shown that many heavy metals, industrial chemicals, solvents, pesticides and carcinogens are unaffected by the processes used at US municipal treatment plants. They are still present and active in the sludge as it is shipped off to American farmers to spread on crop land.

That the regs virtually prohibit the use of manure -- while specifically allowing the use of sludge -- is more a testament to the political power of US cities faced with a difficult disposal problem than an indication of the reliance of the FDA on sound science.

Read this issue carefully and see how your operation may have to change because of this focus on microbial contamination. Is it possible for you to comply? Will you have to give up fields, water sources, crops, or procedures? How much will it cost you?

But don’t forget that food safety is more than a fight against pathogens. For us to be truly healthy we must eat food which is grown without toxic chemicals, from pure seed, and in biologically active soil. That is what we as farmers, and our customers as consumers, really want from agriculture.
The Produce Rule Bottom Line

by Jack Kittredge

With significant assistance from http://www.farmtalkksma.org/

The following issues and concerns about the draft FDA regulations are the ones that seem most relevant to Northeastern growers. We recommend that you read this analysis first, then if you feel that your farm (or the one you buy from) would have difficulty meeting these regulations, read the rest of this issue with an eye to understanding the relevant draft requirements better so you can comment on them thoughtfully and practically.

Agricultural water includes:
• Irrigation water applied using direct water application methods (not drip)
• Water used for preparing crop sprays
• Water used for washing crops
• Water used for washing or cooling harvested produce
• Water used to prevent dehydration of produce

Agricultural water requirements:
• Water that contacts covered produce during growth must come from a source with a CFU of E. coli per 100 ml sample, and no more than an average of 126 CFU per 5 samples.
• Water that contacts exposed produce during or after harvest must have no detectable levels of E. coli per 100 ml sample.
• Water that contacts harvested produce or before harvest must be tested every year.
• Surface water must be tested every 7 days.
• Agricultural water can be treated with antimicrobials in place of testing, but at the current time none are EPA approved for use in irrigation.
• Wash water must be changed frequently enough to avoid contamination, or treated with sanitizer. If using a sanitizer, records of pH, temperature, and sanitation must be kept.
• Hand washing stations must use soap and potable water, not hand sanitizer.

Concerns with the Water Regulations

Testing water is problematic and lab analysis is expensive. E. coli tests can easily run upwards to $50/ sample if they are not done overnight. Farmers using overhead irrigation from rivers, ponds and streams for small fruit and vegetables could be paying $600 per pump year for a 12 acre growing season. Currently there is no alternative on-farm water testing kit available.

Concerns About Sanitation, Tools, and Buildings

Most family farms that do seasonal vegetable production do not have the sophisticated high-tech/high cost greenhouse structures that eliminate all condensation issues. The capital cost for that would be prohibitive.

Even then, how do you go about in working in NOT handling the cucumber, tomatoes or lettuce, and not brushing up against the vines, leaves and fruit?

Worker Health and Hygiene

Farms and packing house workers must be trained in personal hygiene. Toilet facilities must be readily accessible, clean, and supplied with toilet paper. Hand-washing facilities must be close to toilet facilities and supplied with potable running water, hand soap, and clean single use towels. This means that:

• Growing must be trained in hand washing and food hygiene and handling
• Workers must take steps to avoid contact with animals (other than working animals) and wash their hands if they must work with produce after handling animals.

Concerns about Health and Hygiene Mandates

Costs will be added at this level. A person who will train employees will have to Likewise be trained.

Farms will have to have a formal system for handling visitors (cross contamination).

Port-a-potties and hand washing stations with portable water ($80/mo.) will need to be supplied close to all packing sheds and fields near a toilet.

Produce Safety Rule Exemptions

The exemptions section is confusing. At first blush it looks like most farms would be exempt from the produce safety rule, but then other rules seem to capture farms in the exemptions. The EPA states that nationwide only 149,000 farms will be exempt from this new law, so read the fine print!

Below are the Produce Safety Rule exemptions:

• If you sell less than $25,000 of food per year (averaged over three years), you are exempt from the rule. (Well, we are not sure how this works but it seems that you keep three years of sales records to prove you qualify for the exemption.)
• If you sell between $25,000 and $500,000 of food (averaged over three years), AND more than half of your sales are to qualified end users (consumers, restaurants, or retail food establishments) within 275 miles of your farm, you qualify for a partial exemption. If 275 miles takes you across a state or national border, that is okay. If you sell more than $500,000 OR under half of your sales are to qualified end users, you’re not exempt. To comply with the Partial Exemption you must:
  • Keep sales records to prove you are exempt.
  • Label covered produce with your business name and address (including street address or post office box, city, state, and zip).
  • When a label is not required on produce, the farm must prominently display (on sign or otherwise), at the point of purchase, the name and full business address of the farm where the produce was grown.

For the definition regarding sales of food, “food” means anything edible by a human or an animal.

Concerns with Produce Safety Rule Exemptions

The FDA food definition means you must aggregate all your crops, not just produce, into total annual sales to determine the exemption sales level. Many farms seasonally purchase crops from other locations to meet their market. The FDA views that and regrettably, that practice will make you lose your exemption.

“Mixed farm” facilities are farms which also process some food for value-added sales. The regs have provisions beyond the Produce Rule for mixed farm facilities and if they define your farm as a facility it will cost you your exemption.

Good Luck!!
The proposed rule establishes separate Preventive Controls. Farmers would have to implement the provisions in FSMA and are not yet final. Currently, FDA is requesting comments on two proposed regulations:

- Standards for produce production (Produce Rule),
- Equipment, tools, and buildings: The proposed rule sets requirements for equipment and tools that come into contact with produce, as well as for buildings and other facilities.

The plan must document the provisions in FSMA and are not yet final. Currently, FDA is requesting comments on two proposed regulations:

- Standards for produce production (Produce Rule),
- Equipment, tools, and buildings: The proposed rule sets requirements for equipment and tools that come into contact with produce, as well as for buildings and other facilities.

Training: The proposed rule requires training for supervisors and farm personnel who handle produce covered by the rule.

Sprouts: The proposed rule establishes separate standards for sprout production, including treatment of seed before sprouting and testing of spent irrigation water for pathogens.

The new requirements include maintaining and implementing a written food safety plan that includes:

- Hazard Analysis: The plan must identify and evaluate hazards for each type of food manufactured, processed, packed, or held at the facility.
- Preventive Controls: The plan must identify preventive controls that significantly minimize or prevent hazards. Preventive controls include process controls, food allergen controls, sanitation controls, and a recall plan.

- Monitoring Procedures: The plan must document procedures to ascertain that preventive controls are consistently performed.
- Corrective Actions: The plan must identify steps to take if preventive controls are not adequately implemented, to minimize the likelihood of problems reoccurring, to evaluate the food for safety, and to block problem food from entering commerce.
- Verification: The plan must spell out verification activities and document that preventive controls are effective and consistently implemented.

It is critical that organic farmers and consumers who care about where our food comes from write comments to FDA about the proposed regulations to ensure that FDA correctly implements FSMA. Learn more below about the two rules, and then submit your own comments to FDA!

What is the Produce Rule?

The proposed Produce Rule sets forth new standards for growing, harvesting, packing, and holding of produce. The standards apply to fruits and vegetables normally consumed raw, such as apples, carrots, lettuce, onions, and tomatoes. The proposed Produce Rule does not apply to produce rarely consumed raw (such as winter squash) or produce grown for personal consumption.

The proposed Produce Rule establishes standards for:

- Agricultural Water: Farmers would have to ensure that water that is intended or likely to contact produce or food-contact surfaces is safe and of adequate sanitary quality, with inspection and periodic testing requirements.
- Biological Soil Amendments of Animal Origin: The proposed rule specifies types of treatment, methods of application, and time intervals between application of certain soil amendments — including manure and composted manure — and crop harvest.
- Health and Hygiene: Farm personnel would have to follow hygienic practices, including hand washing, not working when sick, and maintaining personal cleanliness.
- Domesticated and Wild Animals: With respect to domesticated animals, the proposed rule would require certain measures, such as waiting periods between grazing and crop harvest, if there is a reasonable probability of contamination. With respect to wild animals, farmers must monitor for wildlife intrusion and not harvest produce visibly contaminated with animal feces.
- Equipment, tools, and buildings: The proposed rule sets requirements for equipment and tools that come into contact with produce, as well as for buildings and other facilities.
- Training: The proposed rule requires training for supervisors and farm personnel who handle produce covered by the rule.

What is the Preventive Controls Rule?

The proposed Preventive Control Rule sets forth new requirements and updates existing requirements for facilities that manufacture, process, pack, or hold human food. Certain on-farm activities may classify a farm as a “facility” subject to the Preventive Controls Rule.

New Requirements

The new requirements include maintaining and implementing a written food safety plan that includes:

- Hazard Analysis: The plan must identify and evaluate hazards for each type of food manufactured, processed, packed, or held at the facility.
- Preventive Controls: The plan must identify preventive controls that significantly minimize or prevent hazards. Preventive controls include process controls, food allergen controls, sanitation controls, and a recall plan.

- Monitoring Procedures: The plan must document procedures to ascertain that preventive controls are consistently performed.
- Corrective Actions: The plan must identify steps to take if preventive controls are not adequately implemented, to minimize the likelihood of problems reoccurring, to evaluate the food for safety, and to block problem food from entering commerce.
- Verification: The plan must spell out verification activities and document that preventive controls are effective and consistently implemented.

A facility is required to maintain a written food safety plan, and to keep records of preventive controls, monitoring, corrective actions, and verification. Only an individual qualified either through training or experience could write the plan. Food safety plans would be reassessed every three years, or more frequently if there are problems.

Updated Requirements

The proposed Preventive Control Rule also updates Current Good Manufacturing Practice (GMP) requirements. Updates include clarifications on protections against cross-contact of food by allergens. Facilities that are exempt or subject to modified requirements in the new requirements for hazard analysis and preventive controls would generally be subject to GMP requirements.

Who is Affected?

Farmers and business owners nationwide are reporting tremendous confusion in determining if they might be impacted by these rules. If you are uncertain, you are not alone! One major concern about these draft rules is that they are complex and confusing for producers.

If you operate a business that grows and sells fresh produce – and/or processes, packs, manufactures, or holds food – you should read the following information.

The Natural Farmer
For Producers and Processors,

• Do you grow, harvest, pack, or hold (store) fruits or vegetables? If yes, you may be affected by the Produce Rule.
• Do you process, manufacture, pack, or hold (store) human food? If yes, you may be affected by the Preventive Controls Rule.
• Do you do BOTH the above? If yes, you may be affected by BOTH the Produce Rule and the Preventive Controls Rule.

For Consumers,

If you’re a consumer, these rules could, over the long term, impact the ability to you are able to find and purchase in your community. The proposed rules may also increase the costs of purchasing fresh fruits and vegetables. Ultimately, we want to ensure a safe and affordable food supply, strong on-farm conservation of natural resources, and thriving family farms and small value-added farm and food businesses.

The following distinctions are based on the produce operations will be subject to modified requirements through the Produce Rule. There are two mains ways by which a produce operation is subject to modified requirements. 1. If the produce will undergo additional commercial processing that kills harmful microorganisms, then the produce is not covered but you are subject to the recordkeeping requirements and the compliance and enforcement requirements of the Produce Rule. 2. If your farm on average over the previous 3 years has less than $500,000 in gross annual sales AND the majority of the food is sold directly to a “qualified end-user,” then you must:

Please note: these rules DO NOT affect home gardeners who grow food for personal consumption.

Production — Who is Covered?

• Produce that is rarely consumed raw (e.g., potatoes, turnips, winter squash)
• Produce that is not in its raw or natural state (i.e., produce that receives additional processing and that would be subject to the Preventive Controls rule)
You are NOT covered by the Produce Rule if the average annual monetary value of the food you sold during the previous 3-year period is no more than $25,000.

Modified Requirements

A number of operations will be subject to modified requirements through the Produce Rule. For Producers and Processors, the following distinctions are based on the produce rule and may change in the final rule. Farms are likely to fall in one of three categories: 1) exempt from the Produce Rule, 2) subject to modified requirements under the Produce Rule, or 3) subject to full requirements of the Produce Rule.

Exemptions from the Produce Rule

Produce that is NOT covered by the Produce Rule includes:

• Produce grown for personal or on-farm consumption
• Produce that is rarely consumed raw (e.g., potatoes, turnips, winter squash)
• Produce that is not in its raw or natural state (i.e., produce that receives additional processing and that would be subject to the Preventive Controls rule)
Please note: these rules DO NOT affect home gardeners who grow food for personal consumption.
FARMERS ARE THE HEART OF HORIZON®

Dedicated organic advocates, our 2012 HOPE Award recipients are Peter and Anita Ruegemer and their family, of Villard, Minnesota. The HOPE Award honors the Ruegemers for sharing their passion for organic farming and for serving as role models for other farmers in their community.

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"A "qualified end-user" is a consumer, or a restaurant or retail food establishment that is located in the same state as the farm that produced the food, or not more than 275 miles from that farm."

Completely Subject to the Produce Rule

You are completely subject to the requirements of the Produce Rule if you grow, harvest, pack, or hold produce that is usually consumed raw and you do not fall under the categories for exemptions or modified requirement.

Preventive Controls Rule – Who is Covered?

At the heart of trying to understand whether farms will be subject to the Preventive Controls rule is the definition of a “facility.” At this point there is still a lot of confusion about the activities conducted by a farm that might trigger the FDA’s definition of a facility. This is a large gray area in the proposed rules.

Do You Operate a Facility?

You operate a facility if you manufacture, process, pack, or hold food for consumption in the U.S. Many activities fall under the definitions of manufacturing and processing, and the key distinction for FDA seems to be whether you are transforming a product in any way. Manufacturing and processing activities always include:

• Irradiation
• Cutting/coring/chopping/slicing
• Canning
• Coating with things other than wax/oil/resin
• Drying that creates a distinct commodity
• Artificial ripening
• Pasteurizing/homogenizing
• Infusing
• Distilling
• Salting
• Smoking
• Grinding/milling
• Freezing
• Slaughtering animals or post-slaughter operations

For other manufacturing or processing activities, FDA then makes the distinction based on whether you are conducting the activities on your own agricultural products (“raw agricultural commodities”) or someone else’s agricultural products. This same principle also applies to the definitions of “packing” and “holding.”

Information about Coverage for Facilities

The Preventive Controls rule has two main parts:

1. New requirements for hazard analysis and risk-based preventive controls; and
2. Revisions to existing Current Good Manufacturing Practice (GMP) requirements.

Coverage under these two parts must be considered separately because certain facilities are subject to one and not the other.

Are You Covered by the New Requirements for Hazard Analysis and Risk-Based Preventive Controls (HARPC)?

Exemptions from the New HARPC Requirements

Exemptions from the new HARPC requirements are as follows:

• Facilities that manufacture products covered by separate regulations:
  o Juice
  o Seafood
  o Dietary supplements
  o Alcoholic beverages
  o Low-acid canned foods (only with respect to microbiological hazards)
• Facilities such as grain elevators and warehouses that are solely engaged in storing agricultural commodities (other than fruits and vegetables) intended for further processing using FDA’s definition of a facility (see the accompanying list of those proposed low-risk activities on page B-9)
• Farms are not covered by the new requirements unless they trigger the “facility” definition

Facilities Subject to Modified HARPC Requirements

Two main types of facilities are subject to modified HARPC requirements:

1. A very small business (FDA has not yet settled on a definition for “very small business”): FDA is proposing either less than $250,000, less than $500,000, or less than $1 million in total annual sales of food) must maintain certain records and certify that:
   a. It qualifies for modified requirements, AND
   b. It is implementing and monitoring preventive controls OR complying with applicable non-Federal food safety law.
2. If the facility on average over the previous 3 years has less than $500,000 in gross annual sales AND the majority of the food is sold directly to a “qualified end-user,”* then the facility must maintain certain records and must certify that:
   a. It qualifies for modified requirements, AND

puzzle solution from page 1
Introducing GRANDEVO®, a unique, broad-spectrum, biological insecticide/miticide. You’ve got tough pest management challenges. GRANDEVO meets them head on with a dynamic new approach. It controls today’s worst sucking and chewing pests—with complex modes of action that enhance resistance management. Added up, it’s a breakthrough unlike anything you’ve ever seen.

Go to www.marronebio.com/grandevo for more.
b. It is implementing and monitoring preventive controls OR complying with applicable non-Federal food safety law and must display a label or sign with business information at the point of sale.

Facilities Subject to the Complete HARPC Requirements
Unless a facility qualifies for the exemptions or modified requirements above, then it is subject to the complete HARPC requirements.

Must You Comply with Current Good Manufacturing Practices?
If you operate a facility, you almost certainly must already comply with current Good Manufacturing Practices (GMPs). The only facilities that FDA exempts from current GMPs are facilities such as warehouses and grain elevators that store raw agricultural commodities (including fruits and vegetables) intended for further distribution or processing.

Be Heard!
There is still a lot of confusion about what activities trigger the definition of a facility and the requirements for different facilities. Learn more about the issues and make a comment today!

Read the Rules
They aren’t exactly beach vacation reading, but if you think you may be affected it is in your best interest to read and analyze them yourself! Farmers and processors who have a direct stake in these rules need to read them and start asking questions about what they might mean for their businesses. The FDA website on the FSMA is at http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm. Click on the appropriate rule page in “Food/GuidanceRegulation/FSMA/default.htm” – either the Produce Rule or the Preventive Controls Rule.

Produce Rule Issues to be Aware of:
• Manure and Compost
• Grazing and Conservation Practices
• Wildlife Habitat
• Water Testing
• Recordkeeping
• Exemptions and Modified Requirements
• Withdrawal of a Qualified Exemption
• Costs to Producers and Consumers
• Farm Registration

Preventive Controls Rule Issues to be Aware of:
• Definitions of a facility, packing, and holding
• Impact on food hubs and certain community-supported agriculture operations
• Exemptions and Modified Requirements
• Withdrawal of a Qualified Exemption
• Costs to Producers and Consumers
• Facility Registration

How Do I Comment on the Rules?
The best way to comment on the proposed rules is through the government website Regulations.gov, which hosts the proposed rules for viewing and a form the public can use to submit comments for consideration. The process can be a little bit confusing; these instructions will help you understand how it works:
2. Click on the appropriate rule page in http://www.Regulations.gov – either the Produce Rule or the Preventive Controls Rule. You can comment on both rules, but you must comment separately. If you’re not certain which issues apply to which rule, refer to our explanation of the rules and issues pages. Some issues affect both rules – this means you’ll have to submit a separate comment on each form for each rule if you want to comment on that issue.
3. Click on the “Comment Now!” button on the page.
4. Double-check that you are commenting on the correct rule – the docket number for the Produce Rule is FDA-2011-N-0921 and the docket number for the Preventive Controls is FDA-2011-N-0920! Enter your personal and business information under Section 1, “Enter Information.”
5. Enter your comments into the box. We strongly recommend you pre-draft your thoughts ahead of time offline, using a word processor like Word or good old-fashioned pen and paper! Note that there is a 6000-character limit – this is about one page of single-spaced typed text. If you think you have more to say, you can upload a separate document with your comments instead.
6. Click the “preview comment” link to ensure everything is accurate. You cannot edit your comment once you submit it!
7. Click “submit” to officially submit your comment to FDA.
   a. Did you do it? FDA will read every comment submitted. They may not respond to each comment individually but they will address the substance of these public comments publicly once the comment period has closed.
8. A screen will appear with a confirmation number for your comment. Copy this down – you can use it later to ensure your comment was received.
9. Your comment may not appear on the FDA’s public comments pages. Some issues affect both rules – this means you’ll have to submit a separate comment for each rule.

What Should I Say?
Here are some general guidelines to help your comment have its maximum impact:
• Your story matters – be sure to share with FDA why this matters. Are you a farmer? Share how the rules might impact your farm. Are you a consumer? Make sure FDA knows the kind of food you like to buy from farmers and that you want to ensure these rules don’t unfairly burden those farmers.
• Keep it polite and avoid profanity – remember that all comments will become part of the public record and will be read by FDA officials.
• Make sure you have a clear “ask” for FDA – either about a specific issue or, broadly, about the importance of ensuring both safe food and thriving families.
• Do not exactly copy someone else’s comment – for FDA to count your comment, it must be unique. You can make the same or similar points as another person, but you do need to add your own perspective as much as possible.

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A Summary of the Proposed FDA Rule

From the Executive Summary of FDA’s Proposed Standards for the Growing, Harvesting, Packing, & Holding of Produce for Human Consumption

Note from editor: What follows is from page 3504 Federal Register/ Vol. 78, No. 11 / Wednesday, January 16, 2013, with additional comments from Dr. Luke LaBorde, Pennsylvania State University, as published in Organic Matters, Spring 2013. The Produce Rule itself is 144 pages of detailed language. The FDA estimates that 1.75 million cases of foodborne illness would be prevented annually by this regulation, with an annual benefit of $1.04 billion. They estimated that compliance with the proposed rule will cost domestic farms $459.6 million. The estimated average annual cost for very small farms (less than $250,000 in annual revenues) is $4,697, $12,972 for small farms (between $250,000 and $500,000 in annual revenues) and $30,566 for large farms.

Scope of Coverage of the Proposed Rule

The proposed rule would apply to both domestic and imported produce. However, as explained in the remainder of this document, the proposed rule contains several exemptions:

- The proposed rule would not apply to certain specified produce commodities that are rarely consumed raw.
- The proposed rule also would not apply to produce that is used for personal or on-farm consumption, or that is not a raw agricultural commodity.
- The proposed rule would provide an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms (e.g. a “kill step”) as long as certain documentation is kept.
- The proposed rule would not cover farms that have an average annual value of food sold during the previous three-year period of $25,000 or less.
- The proposed rule would provide a qualified exemption and modified requirements for farms that meet two requirements: (1) The farm must have food sales averaging less than $500,000 per year during the last three years; and (2) the farm’s sales to specified end-users must exceed sales to others. 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 as the farm and not more than 275 miles away. Instead, these farms would be required to include their name and complete business address either on the label of the produce or food-contact surfaces (proposed § 112.3c).
- Establish requirements for inspection, maintenance, and follow-up actions related to the use of agricultural water, water sources, and water distribution systems associated with growing, harvesting, packing, and holding of covered produce (proposed §§ 112.42 and 112.46).
- Comment—Maximum average E. coli levels of 126 cells per 100 milliliters has been proposed for irrigation water that can contact the edible part of the crop. Water used for post harvest operations face more stringent standards; no detectable levels of E. coli are allowed.

- Require treatment of agricultural water if you know or have reason to believe that the water is not safe and of adequate sanitary quality for its intended use, including requirements for treating such water and monitoring its treatment (proposed § 112.43);
- Establish specific requirements for the quality of agricultural water that is used for certain specified purposes, including provisions requiring periodic analysis and testing for certain contaminants (with exemptions provided for use of public water supplies under certain specified conditions or treated water), and requiring certain actions to be taken when such water does not meet the quality standards (proposed §§ 112.44 and 112.45); and provide for alternative requirements for certain provisions under certain conditions (proposed § 112.12); and
- Require certain records, including documentation of inspection findings, scientific data or information relied on to support the adequacy of water treatment methods, treatment monitoring results, water testing results, and scientific data or information relied on to support any permitted alternative to requirements (proposed § 112.50).

Summary of the Major Provisions of the Regulatory Action

The proposed rule would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. We propose new standards in the following major areas:

• Worker Training and Health and Hygiene
  - Establish qualification and training requirements for all personnel who handle (contact) covered produce or food-contact surfaces and their supervisors (proposed §§ 112.21, 112.22, and 112.23);
  - Require documentation of required training (proposed § 112.30); and
  - Establish hygienic practices and other measures needed to prevent persons, including visitors, from contaminating produce.

• Agricultural Water
  - Require that all agricultural water must be of safe and sanitary quality for its intended use (proposed § 112.41). Agricultural water is defined in part as water that is intended to, or likely to, contact the horticulturally portion of covered produce or food-contact surfaces (proposed § 112.3c).
  - Establish requirements for inspection, maintenance, and follow-up actions related to the use of agricultural water, water sources, and water distribution systems associated with growing, harvesting, packing, and holding of covered produce (proposed §§ 112.42 and 112.46).
  - Comment—Maximum average E. coli levels of 126 cells per 100 milliliters has been proposed for irrigation water that can contact the edible part of the crop. Water used for post harvest operations face more stringent standards; no detectable levels of E. coli are allowed.
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  - Require certain records, including documentation of inspection findings, scientific data or information relied on to support the adequacy of water treatment methods, treatment monitoring results, water testing results, and scientific data or information relied on to support any permitted alternative to requirements (proposed § 112.50).

• Biological Soil Amendments
  - Establish requirements for the growing, packing, and holding of organic produce except in compliance with EPA regulations.
  - Establish specific requirements for the quality of agricultural water that is used for certain specified purposes, including provisions requiring periodic analysis and testing for certain contaminants (with exemptions provided for use of public water supplies under certain specified conditions or treated water), and requiring certain actions to be taken when such water does not meet the quality standards (proposed §§ 112.44 and 112.45); and provide for alternative requirements for certain provisions under certain conditions (proposed § 112.12); and
  - Establish application requirements and minimum application intervals for untreated and treated biological soil amendments of animal origin (proposed § 112.25); and provide for alternative requirements for certain provisions under certain conditions (proposed § 112.12); and
  - Comment—At least a 9-month interval (270 days) would be required between applications of raw animal manure to produce fields and harvesting if there is a possibility that the manure may contact the produce. Composted animal manures can be applied from 0 to 45 days before harvest depending on whether or not it can contact the crop. Growers, or commercial compost suppliers, must provide proof through laboratory testing that the composting process was adequate to make it safe to use.

• Domesticated and Wild Animals
  - If animals are allowed to graze or are used as working animals in fields where covered produce is grown and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, require, at a minimum, an adequate waiting period between grazing and harvesting for produce and growing area that was grazed, and measures to prevent the introduction of known or reasonably foreseeable disease sources into the fields.

Note: The comments in italics are additional comments from Dr. Luke LaBorde, Pennsylvania State University, as published in Organic Matters, Spring 2013. The comments are included for informational purposes only and do not reflect proposed changes in the final rule.
hazards into or onto covered produce (proposed § 112.82); and
Comments – Working animals, such as mules and horses, are allowed in produce fields as long as the grower can demonstrate that they have taken adequate measures to prevent contamination. If animals graze in areas intended for produce growing, the waiting period specified for application of raw manure (270 days) would apply.

* If under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce, require monitoring of those areas that are used for a covered activity for evidence of animal intrusion immediately prior to harvest and, as needed, during the growing season (proposed § 112.83).

Comments – Organic regulations require operators to prevent contamination of crops from animal materials and to document contamination prevention methods in their Organic System Plan. Conservation of biodiversity is an integral part of organic production. Many organic farms actively manage their farms to increase biodiversity due to its many benefits, such as pest management.

• Equipment, Tools, and Buildings

* Establish requirements related to equipment and tools that contact covered produce and instruments and controls (including equipment used in transport), buildings, domesticated animals in and around fully-enclosed buildings, pest control, hand-washing and toilet facilities, sewage, trash, plumbing, and animal excreta (proposed §§ 112.121–134); and

Comments – Partially enclosed packing buildings are acceptable if the grower or packer takes precautions to prevent birds and other pests from becoming established in the buildings.

* Require certain records related to the date and method of cleaning and sanitizing equipment used in growing operations for sprouts, and in covered harvesting, packing, or holding activities (proposed § 112.140).

Comments – Facility pest management is a critical component of an operator’s organic system plan and should include measures to prevent pests from entering facilities.

• Sprouts

* Establish measures that must be taken related to seeds or beans for sprouting (proposed § 112.141); and

* Establish measures that must be taken for the growing, harvesting, packing, and holding of sprouts (proposed § 112.142);

* Require that you test the growing environment for Listeria spp. or L. monocytogenes and that you test each production batch of spent irrigation water or sprouts for E. coli O157:H7 and Salmonella species and take appropriate follow-up actions (proposed §§ 112.143, 112.144, 112.145, 112.146); and

* Require certain records, including documentation of your treatment of seeds or beans for sprouting, a written environmental monitoring plan and sampling plan, test results, and certain methods used (proposed § 112.150). As proposed, the effective date is 60 days after a final rule is published, however, we are providing for a longer timeline for farms to come into compliance. Small businesses (i.e., those subject to proposed part 112 and, on a rolling basis, the average annual monetary value of food sold during the previous three-year period is no more than $500,000) would have three years after the effective date to comply; for some of the water requirements, they would have five years. In addition, very small businesses (i.e., those subject to proposed part 112 and, on a rolling basis, the average annual monetary value of food sold during the previous three-year period is no more than $250,000) would have four years after the effective date to comply; for some of the water requirements, they would have four years to comply. All other farms would have two years after the effective date to comply; for some of the water requirements, they would have four years to comply.

Comments – Organic regulations require operators to prevent contamination of organic sprouts from prohibited materials or pathogenic organisms.

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DEPARTMENT OF AGRICULTURE

OMRI LISTED
FDA Food Safety Rules Generate Varied Reactions
by Jack Kittredge

Based on information from the Washington Post, the Springfield Republican, Grant, Food Safety News, Reason, LancasterFarmland.com, kcra.com, kwwl, Weston A. Price Foundation

Tree fruit growers: Regulations unnecessary and costly

Growers subject to the proposed FDA produce rules could face a variety of new responsibilities, including regular testing of irrigation water, sanitizing canvas fruit-picking bags and keeping animals away from crops. Many tree fruit growers worry about the cost of such measures and say they would offer few safety benefits.

They argue that the FDA should focus more on foods that have caused deadly outbreaks, such as spinach and cantaloupes, and less on fruits that have a virtually flawless safety record, grow above the ground and, in some cases, have protective skins or rinds. “Our product is quite safe,” said Phil Glaize, a third-generation farmer and owner of Glaize Apples in Winchester, Va. “We’re perfectly willing to look at ways to make it safer. However, what’s being proposed is very onerous and expensive.... The costs would end up getting passed on to the consumer, if we didn’t go out of business first.”

Such wariness persists on orchards from the Shenandoah Valley to the Yakima Valley. “I’ve had a couple guys call and say, ‘I’m 55 years old. If this goes into effect, I just want to get out,’” said Chris Shenandoah Valley to the Yakima Valley. “I’ve had a couple guys call and say, ‘I’m 55 years old. If this goes into effect, I just want to get out.’”

All this is going to be significant,” he said.

Even farms that are exempt would incur some costs for learning the contents of the rule and figuring out which parts may or may not apply to them. For example, if a farm qualifies for an exemption because they grow potatoes — which are rarely, if ever, eaten raw — not because they grow tomatoes that are primarily processed into canned tomato sauce, it would still need to keep documentation on which company received its product.

Food Freedom advocate Baylen Linnekin: Proposal costly and ineffective

The new rules would cost about half a billion dollars per year. The cost of FSMA will be borne by farmers and food producers of all sizes. But will the proposed rules make America’s food supply — already quite safe and getting safer thanks to conscientious farmers, producers, and sellers of all sizes, vigilant watchdog groups, and eagle-eyed food-safety lawyers — any safer?

According to the Center for Science in the Public Interest FDA food safety inspections dropped by 47 percent between 2003 and 2006. During that same period, according to CDC data, rates of infection from bacteria like Listeria were flat and below traditional averages. Despite the misconception that cases of foodborne illnesses are mushrooming, the CDC reports that there has been a general downward trend in foodborne infections.

In other words, foodborne illness cases have been decreasing without the FSMA, and fewer FDA inspections over a period of several years did not translate into any detectable difference in cases of foodborne illness.

Pennsylvania Growers: Rules not workable

“Upset doesn’t begin to explain how I feel about the proposed produce regulations,” said Brian Snyder, executive director of the Pennsylvania Association for Sustainable Agriculture, said many farmers raising only a few acres of produce could exceed the exemption since the government takes into account total food sales and that could include a major dairy or beef operation that put the farm over the $500,000 threshold. “That means the $500,000 rule isn’t even meaningful,” he said.

Another issue is manure application, which the rule specifies must be done at least nine months before vegetable harvest. Bill Troxell, executive secretary of the Pennsylvania Vegetable Growers Association said that contrasts with many existing “good agricultural practice,” or GAP programs, which allow for a shorter interval, three months in most cases. The longer application interval would create problems on some farms and could ruin crop rotation schedules. “So, if a crop is harvested in the beginning of July, manure would have to be applied by October of the previous year. In those cases, that’s before the existing crop is actually harvested.”

Jeff Stoltzfus, adult ag educator for the Eastern Lancaster County School District, who works with many Plain Sect producers, also had concerns. He’s concerned with the amount of recordkeeping that will be required of producers. “Our guys are one-man operations. The farmer is doing everything. He’s worried about marketing. He’s worried about plant health,” Stoltzfus said. “Keeping food safety records...all that he’s doing, compared to a larger operation that can put someone in charge of that. I think the management burden that will be put on our farmers is going to be significant,” he said.
California Farmers: A financial hit for farmers

Bruce Fry, president of the San Joaquin Farm Bureau Federation, feels that the farmers he deals with are already following the FDA basic rules – requiring farm workers to wash their hands, making sure irrigation water is clean, ensuring that animals stay out of fields.

“A lot of the buyers are mandating that you are doing these things anyway,” he says. “But you have to hire someone to put that plan together. Then you have to make sure you’re doing all those things that they are asking you to do.”

The FDA said the proposed rules could cost large farms $30,000 a year. The endeavor has the potential to impact the cost of food, but Fry believes the reality is that farmers will absorb the cost.

Tom Laskawy, Grist: White House gutted the new rules

“During a drawn-out review period, the White House Office of Management and Budget (OMB) rewrote the rules for new safety protocols for food producers drafted by FDA. When Congress passed the food safety law, it for the first time required food producers to design, implement, and test risk-based food safety plans. The law required testing for contamination in food processing facilities, and then testing the foods themselves. The OMB revised the mandate for verified food safety plans and dropped virtually all the testing requirements, turning them into voluntary protocols. (We know how well it works out when the food industry regulates itself.)

Without requirements for testing and verification of safety plans, the FDA will remain powerless to stop things like the deadly 2011 listeria outbreak in cantaloupe caused by shockingly unsanitary storage conditions at a Colorado farm. Had that farm been forced by law to produce a safety plan and then to have that plan verified, much less to have its produce tested, the people who died would likely be alive today. Thanks, OMB.

I asked food safety superlawyer Bill Marler (managing partner of the Seattle law firm Marler Clark and a key player in the lawsuit against Jack in the Box over E. coli poisoning in its hamburgers that killed four children in 1993) for his take on all this. He pointed out that the food industry by and large supported the testing requirements because they leveled the playing field between good corporate citizens that took food safety seriously and bad guys, like the Peanut Corporation of America, that did not. Then along comes OMB “opening up a loophole for people to ignore” the new law, Marler said.

The revelation about the OMB’s changes to the law comes from an unlikely source — the federal government. Some good soul in the Department of Health and Human Services (the parent agency of the FDA) posted documents on a government website that detailed the exact revisions OMB made to the food safety regulations. Ownership of these kinds of cuts is typically a well-guarded secret.

Judith McGeary on the Weston A. Price Foundation website: Paperwork, fear of manure, extensive water testing, personnel requirements

“An initial review of the proposed rules has already highlighted many troubling provisions. Both rules include extensive documentation requirements that threaten to swamp farms and food producers in paperwork. In multiple places in the produce safety rule the agency evidences unwarranted fear of animal-based soil amendments, which include compost and compost teas. For example, if the compost is not “treated” consistent with FDA’s standards, there is a nine-month waiting period required between applying the compost and harvesting the crop. In practice, this could cripple mid-scale growers’ ability to use any manure-based composts or compost teas.

“The proposed regulations impose extensive testing requirements for water used in agricultural operations, and personnel requirements that turn the current voluntary Good Agricultural Practices (GAP) standards into regulatory requirements.”

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Since the average net cash income for farmers nationally was 10% of sales in 2011, the costs of complying with the FDA rules represents a severe burden that will put many small farms out of business.

Problems in the rule –

• if you apply raw manure to a field, you’ll have to wait 9 months before harvesting any crops from that field.
• if you irrigate with surface waters, you’ll have to test that water once per week, or treat it with chemicals.
• if you grow crops in a hoophouse, you’ll have to keep the floors clean!
• if you are a food hub and you put labels on bags of raw produce, you are a ‘manufacturing’ facility.

Clearly, the light is not over. If we want local, organic food and farming to thrive, we need to mobilize our families, friends, and neighbors; farmers, foodmakers, and customers, to comment on these rules and tell FDA to keep its hands off local food. The feds must hear from us if we are going to get the changes we need to fix these flawed and illogical rules.
Food Safety Taken Seriously at Fellenz Family Farm

by Jack Kittredge

The Finger Lakes region of New York is among the most fertile agricultural areas of the northeast. When troops were sent by George Washington under John Sullivan to drive Native Americans from the region, a number of the soldiers noted the quality of the crops that were growing there and returned to set up their own farms.

Half way between Syracuse and Rochester, just a few miles north of Geneva, sits the small community of Phelps, NY. A dozen years ago technical engineer and middle manager Andy Fellenz gave up a career at International Paper to move his wife and four kids to an old farm there. They had gone to farming conferences and read farming books for about five years, and dreamed of running an organic fruit farm, specializing in U-Pick berries and custom cider pressing.

“I figured I had the opportunity to try it,” he recalls, “and it made more sense to do when I was about 40 years old rather than wait until I was 50 or 60 years old. My wife works as a teacher. If she wasn’t working I wouldn’t be able to do this — at the size we are at, and the way we do things, we couldn’t make this farm work as a primary income source for us. We could make it work for a subsistence income, but we have 4 kids and kind of like the middle class lifestyle!”

Fellenz planted over an acre of apples and berries when first moving onto the farm. Then the state changed the rules on cider pasteurization. He didn’t see a way that he could put in pasteurization along with incredibly small-scale personalized juice production. It would have been a $15,000 to $20,000 investment in equipment, he estimates, and he couldn’t see how to make that investment pay.

Also, some of the apple experts he talked with didn’t think he had a chance of getting good crops organically. They told him that Phelps, like most of the northeast, had a lot of apple pests and disease organisms around.

Fortunately, Andy met some people who wanted him to grow crops for a CSA they wanted to organize. That venture seemed, on reflection, to make more sense that the original dream. But the farm couldn’t see a way that he could put in pasteurization along with incredibly small-scale personalized juice production. It would have been a $15,000 to $20,000 investment in equipment, he estimates, and he couldn’t see how to make that investment pay.

“The CSA model has worked well for us,” he reflects. “I enjoy doing a variety of things, having many crops, dealing with customers. My wife, too, has been incredibly supportive and went to farmers markets at first. But after a couple of years the novelty wore off. She keeps the farm stand stocked during the summer. But it is not what she wants. She teaches 9th and 10th graders and really enjoys that.

“I don’t think it will last forever, however,” he adds. “It has some fad aspects to it. We have about 230 members this year – not small, but not real big either. We retain from 60% to 80% of my members here. I figure anything over 70 percent is good. People are going to leave at a certain rate, no matter how well it works for them. People move, their lives change. I’m at the 10 year mark and we have 6 people who have been members from the beginning.”

In 2012 Fellenz had five different CSA season length options. He started them the first week of May and the longest one went until the first week of December. Some ended in early November, others late November. The season length depends on what the people at a CSA drop site want. The sites are at churches. At two sites the CSAs grew out of church projects. For the third the site was just a convenience – the church has a central location and they were willing to let Andy use their space for a nominal cost.

The first pickup is at the Unitarian church. The members are doing it for green living, sustainability, buying local, and a whole curriculum they were working through. One CSA is with a Catholic church. They had a ministry there for God’s creation and the CSA was a project of that ministry. The third one is in Geneva and has faculty or staff of Hobart and William Smith colleges, or the Cornell experiment station in Geneva.

The farmers pack a portion of each share and then set up a farmers market display for the rest. People choose several items from the display to fill out their share. So there is always a little member choice in what they get. People like that feature. Fellenz believes, and for him it is easier if he doesn’t have enough of any one thing – like eggplant. He can send it along and some people will choose it.

The Wednesday share, in Geneva, is the biggest. There are over 90 members and they have the various season lengths. Since many members are academics, this lets them join just for the summer, just for the fall if they are away all summer, or pick a season that ends in late October or one that goes until December. They can also have a pre-season in May for 2 weeks before everyone else starts. That gives him a chance to better utilize his high tunnels.

It’s an all greens share, perhaps with asparagus, and gives the hardcore members a chance to start the season early.
For the Friday distribution at the Church of the Transfiguration the shares are capped and closed off at whatever they have on opening day. With the other CSAs Andy will take late shares and just pro-rate the cost.

Fellenz built a little tiny greenhouse at first, then decided to try a high tunnel. These worked well, so the next year he put in two more and rotated crops through them. Then a garden center went out of business and he bought a 17 x 96 house. But he soon realized that didn’t work as well for production as even bigger houses where the ratio of inside to edge area is a lot better. Bigger houses don’t have as much edge effect in terms of cold weather, and also are easier to maneuver a tractor in. Without the high tunnels Andy doubts he could be doing 230 shares. Three small greenhouses are heated, but none of the high tunnels are.

“We use the high tunnels mostly now for rotations of greens,” he says. “Rather than do cut and come again we’ll do full sized plants and take them out and transplant in another crop of lettuce. I’d like to grow out some stuff over the winter and then next year I could do a longer season.

“We have overhead irrigation in these tunnels,” he continues. “It is all on a timer. These greens are out of here every 5 weeks. It is much less labor for me if I’m running the overhead on them than having to take up the drip every time to replant. And when I’m in here cultivating someone is sure to nick the drip. We’ll do drip for anything that is in the house full season, like eggplant. We mulch over it. We rotate our tomatoes through the tunnels and try to make sure there is enough time to dissipate any soil borne disease affecting tomatoes before they are back in.”

Andy uses a Japanese paper pot transplanting system for all his greens. A long strip of paper is used for transplanting the seedlings which come with the system make planting easily filled with potting soil and a dibble and seedling tray which come with the system. It is cleverly folded in such a way that it opens up into a honeycomb array inside special planter trays. It is really geared to larger farms that aren’t growing disease affecting tomatoes before they are back in.”

“All my greens that are planted out there,” says Fellenz, “come out of trays like this. You get a plant coming up in every cell. You load this tray onto the transplanter and this unwind. Depending on the size of the tray it is either 2, 4, or 6 inches between the plants. You anchor one end, pull the transplanter down the row, and the greens are uniformly spaced. You fill this honeycomb with a potting soil. Here is the dibble board. You press this into the potting soil and it makes indentations to receive the seed. This vibrating tool puts the seed in.

“It has been a game changer for us,” he continues, “in terms of the economics of doing greens. Someone working in a greenhouse is probably seeding 6 trays an hour. There are 264 plants in each of these trays. When you set the plants out in a high tunnel you are probably doing 4 trays per worker hour, including bed prep. That comes to over 1000 plants per worker hour. You set them out at the stage where you would be doing the first cultivation and thinning if you had direct seeded. This gives us one additional cropping cycle in the tunnel each season.”

Andy added an option of a half dozen eggs to his CSA last year. He wanted the chickens for the manure, which he plans to compost with red wiggler worms. He had hoped to sell eggs by the dozen as well. But there are many Mennonite families in the area who sell non-organic eggs for $1.50 a dozen. Andy added an option of a half dozen eggs to his CSA last year. He wanted the chickens for the manure, which he plans to compost with red wiggler worms. He had hoped to sell eggs by the dozen as well. But there are many Mennonite families in the area who sell non-organic eggs for $1.50 a dozen.

Fellenz has been active in learning about food safety issues. He has taken some of the Good Agricultural Practices (GAPs) trainings run by Cornell and has nothing but good things to say about them. He went to some of the informational sessions on GAPs run over the last three or four years and thought there were things he could do better on his farm. Not that he was putting anyone at risk, but GAPs was a tool that would force him to get better, be a little more disciplined about what he was doing on the farm.

“That 2-day class was really worthwhile for me,” he says about the introductory seminars. “Most of the first day was just education and orientation to issues that you might have on your farm. The end of the first day and the entire second day is devoted to helping you write the first draft of a GAP manual that you might use on your farm. They provided a lot of materials that you can reference and steal from. They had resources and inspectors there who you can talk to for advice. It helped to identify what I really needed to include in my farm’s manual and build something that would be usable by me, rather than a cut and paste from someone else’s manual.

“You start off,” he continues, “with a farm description, program implementation, a farm map, traceability – which is pretty much what I do for the organic certification, except for GAP I had to be able to show how I would do a product recall. If there ever was a food safety problem, how can I reach my customers and reach back into my records to identify the suspect material on the farm? We have to show what we do for worker health and hygiene, training for pick-your-own customers, toilet and hand washing facilities, etc. You do an analysis of your farm and ask: ‘Where are your risk issues?’ In my farm it was the people working here. So no glass containers, no eating while harvesting. I’ve never had smokers here. I just don’t allow it. Check your farm and ask: ‘Where are your risk issues?’ In my farm it was the people working here. So no glass containers, no eating while harvesting. I’ve never had smokers here. I just don’t allow it. Check your tools, keep your hands clean, don’t pee in the hedge-row, check the harvest totes and make sure they aren’t soiled, do field dressing and just don’t bring in the outer contaminated leaves.

“The GAPs farm review,” Andy concludes, “is the overall basic evaluation of a farm. You can also get GAP-certified for specific crops, but the program is really geared to larger farms that aren’t growing a lot of different crops. You can’t get certified for...
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mixed vegetables, for example -- it has to be cantaloupe or sweet corn or whatever. But you can get certified for your packing operation or your shipping and transit operation if you have your own trucks. When you apply you indicate which parts of the program you want to be audited for. Everyone has to do a farm review. But otherwise you can pick what makes sense for your operation or what you are being mandated to do by your customers.”

His GAP certification expired in September and Fellenz didn’t renew it this year. He did it initially just to act as a spur to force him to be a little bit smarter. He made some changes in order to be certified and has continued with changes as needed. But he didn’t see a whole lot of value in maintaining the certification at the farm review level. If he did renew it he says he would make some more changes in his packing shed and then certify both at the farm review level and for the packing shed.

One weakness of GAPs for CSAs and mixed vegetable operations like his, Andy feels, is that if you want to be certified for crops, you have to be separately certified for each vegetable. There is an inspection and fee for each one, and they have to be there on the day you are harvesting that crop. That is what they are really interested in – how are you harvesting and handling the crop?

But for the farm and packinghouse certification, they are looking more at the physical environment and the people who are working in the environment, rather than your handling practices for one item. An example is contamination by wildlife.

“I don’t have big wildlife issues here,” Fellenz asserts. “But the inspector wanted me to make sure I knew where wildlife was and what the signs of them in the field would be. If we saw such signs, say of deer in the field, then she wanted me to know what to do. That is all here [he pats his GAPs manual]. We monitor the fields, crops are inspected for signs of damage, damaged produce is culled. We keep our buffer strips mowed and monitor them for dropings. Last year we didn’t have chickens here and had no manure stored on the farm.

“The rodents in the greenhouses,” he adds, “eating plants that are just germinating are a real problem. Here is our trap. We use these in the packing shed and also the greenhouses. It’s just a tin cat. The rodents like to run along the walls so they will run in but they can’t get out. There is a teeter-totter in there. They walk in and it goes down and then pops back up. The window on the top let’s you do a visual inspection to see if you have caught one. It is a nice trap for monitoring. You can just leave it in place without having to bait it and they starve to death in there. What we say in our procedures is that if you start seeing rodents in them you need to start putting out the snap traps and be more aggressive in trying to manage them.”

Harvesting is an area where practices are carefully scrutinized. ‘No eating while harvesting’ is a basic rule for Andy. The biggest risk he has of contamination is hand to mouth produce contact. If someone is eating something and touches his mouth or nose, and then touches the product, whatever he had in his mouth or nose is now on the farm product!

To reduce contamination, Fellenz usually does pretty extensive field dressing on celeriac and leeks. With other vegetable he just strips off the leaves, but those two come in cleaned a little to minimize what is brought into the packing shed.

Also, if an employee uses his own vehicle on your farm, you need to be conscious of it. Has it been somewhere that manure got onto it? Has it got oil and grease in the bed that you are stowing produce into?

Initially, Andy’s help used the bathroom in the house. But not having single use paper towels or a hand dryer, or a log sheet to show regular cleaning, was a bit of a problem. You can have the bathroom in the house, under GAPs, but you need to put the same appropriate care into it that an employee bathroom needs.

“My wife was getting tired of people coming through the house to use the bathroom,” he sighs, “is why we added one to the packing shed.”

Some of Andy’s eggplants in boxes and totes. Cleaning and use of totes in the harvesting and packing operation is carefully discussed in the Fellenz Farm GAP manual. Some of Andy’s totes are reversible so one way they stack, the other way they nest.
The Fellenz Family Farm is a certified organic mixed vegetable and fruit farm. Crops are grown both in the field and high tunnels. All transplants are grown in on-farm greenhouses. Livestock are not kept on the farm.

The farm is located at 1919 Lester Rd., Phelps NY 14532 (Tax map 324089 48.00-29.0000). A rented field is located ~1 mile from the home farm. The rented field is located within tax parcel 48.00-2-31.100. Approximately 5 acres are cropped at 1919 Lester Rd. and ~5 acres are cropped on the rented field. Both fields are primarily sandy loam and gravely loam soils. None of the fields are located in a flood plain or near farms with manure lagoons or other manure storage facilities.

The farm has been certified organic since 2005. The certifier is NOFA-NY Certified Organic LLC. The farm has been managed following organic practices since 2001. Prior to 2001 the field at 1919 Lester Rd. was rented and conventionally farmed producing row crops. The rented field has been farmed organically since 2008. Prior to this, it was not farmed or was in CRP for over 20 years.

Implementation of a Food Safety Program

Food Safety & GAPs Training

Andy Fellenz, the farm owner and person responsible for the GAPs program on the farm, has attended several GAPs and Food Safety training classes. Most recently, he attended the GAPs Training and Food Safety Plan Writing Workshop sponsored by NOFA-NY, Cornell University CEE and the USDA RMA on March 23-24, 2011 in Geneva NY.

All farm employees receive food safety and GAPs training relevant to their work responsibilities.

Farm Map

See Appendix 1 for a farm map and packing house layout diagram.

Traceability Procedures

Our farm utilizes a paper-based traceability system. The system allows us to trace product back to our suppliers and forward to our customers.

Our Greenhouse log details planting dates and seed suppliers

Our Field Log details planting and transplanting dates and planting location

Our Harvest Log details harvest quantity and picking location

Our CSA emails list what product has been included in the CSA shares each week.

By reviewing our records we can trace back from a CSA email to the harvest log which will lead us the appropriate entry on the field log and from there back to the greenhouse log.

Product Recalls

We maintain an email list which allows us to contact all of our CSA customers if necessary.

Worker Health and Hygiene Policy

Drinking water policy: Potable drinking water is provided. A water-jug with paper cups is kept in the packing shed. Employees can use their own plastic or metal containers in the field. If needed, a water jug and cups will be brought into the field. Due to the risk of injury or product contamination if they are broken, glass containers cannot be used in the field or packing shed.

Training: All employees receive training when they start work on the farm and a refresher course at least once a year.

Training includes instruction on all policies and procedures related to worker health and hygiene. Where appropriate, specialized training related to specific jobs, such as anyone who applies pesticide sprays, is provided. All training is documented in the worker training log.

Hand Washing: Everyone must wash their hands before beginning harvesting, working in the Packing Shed, when returning to harvesting or the Packing Shed after taking a break, going to the restroom, eating, or otherwise compromising the sanitary nature of their hands.

First aid procedures: First aid kits are kept in the Packing Shed, Farm Shop and pick up truck. Every one is asked to attend to an injury immediately and to notify Andy or Erin of any injury.

Illness: Any employee who is sick should notify Andy or Erin and not handle fresh produce. If you have any of the following symptoms you cannot harvest or work in the packing shed:

- Diarrhea
- Fever
- Vomiting

Lesions containing pus (including boils or infected wounds, however small) on the hand, wrist, or any exposed body part

Blood and body fluid: If blood or other bodily fluid comes in contact with produce, it must be addressed immediately. Notify Andy or Erin of the injury and where it occurred. The affected area will be cleaned and any affected produce will be disposed of.

Safety during application of chemicals: Only materials allowed for use by OMRI or NOFA-NY may be used. Label instructions must be followed. Personal Protective Equipment (PPE) required for safe handling and use of the material must be used (check label for requirements). All use of chemicals and amendments must be logged. The active log sheets are kept in Greenhouse. Completed log sheets are filed.

Employee Food Safety and Security Empowerment: All employees are instructed to share information they observe regarding food safety and security. If employees see unusual individuals or situations, they should notify their supervisor over the phone. If employees notice pests or other food safety issues, they are encouraged to share this information with their supervisors.

Pick Your Own visitor policy: Pick your own customers receive a verbal orientation regarding the farm, our safety and hygiene policies, use of rest facilities and picking rules before beginning to pick.

Community Supported Agriculture (CSA) Members: All CSA members receive a verbal orientation about the farm and our procedures before beginning their first work day. General information regarding the farm policies is included in the Work Day information sheet provided to all interested members.

Toilet and Hand Washing Facilities

Clean toilet and hand washing facilities are in the house. During U-Pick season a port-a-potty with hand washing station is set up adjacent to the berry patch.

Farm Review

Water Usage

All water used in the farm is potable water. The water is tested annually.

Sewage Treatment

The farm utilizes a septic system for all domestic waste water. Process rinse water is drained separately.

Animals/Wildlife/Livestock

Livestock are not kept on the farm. Wildlife activity is monitored. Crops which show evidence of damage from wildlife are inspected closely and affected produce is culled. Manure is not stored on the farm. Butler strips are kept mowed adjacent to each field.

Manure and Purchased Compost Handling

Small quantities of raw manure are occasionally used on the farm. Any application of manure is limited to areas which will not be planted within 14 days or harvested for at least 120 days. All applications of manure are noted on the applied amendments log. Manure is generally not stored on the farm. In the case of short-term storage it is located away from and lower than crop production areas.

Purchased compost is applied. All purchased compost is obtained from NOFA-NY approved suppliers. All compost applications are noted in the Applied Amendments Log.

On-farm Composting Practices

Compost is not produced on the farm. When materials from the cull pile are applied they are either applied to non-production areas or are applied a minimum of 180 days prior to harvest.

Soils

Our cropland has been farmed for almost 200 years. There are no concerns about previous land use related to microbial contamination of crops. The fields are very well drained and gravelly loams and do not lie in a flood plain.

Traceability

All harvest locations are identified on the harvest log to facilitate traceability.

Field Harvesting and Packing Activities

Field Sanitation and Hygiene

Since beginning the farm in 2002 there have been no significant issues with crop contamination from wildlife at 1919 Lester Rd. The rented field has had issues with deer damage each season. Damaged produce is culled. With the exception of a Porta-Potty, the farm has no other toilet facilities. The U-Pick Port-a-Potty is installed outside of a production area and at a lower elevation than the berry patch. In the event of a spill, the Porta-Potty vendor will be notified and will provide clean-up services.

Field Harvesting and Transportation

Harvest Carts, Totes and Field Packaging

Harvest carts, wagons and a pick-up truck are used to transport harvested product. All produce is harvested into and transported in plastic totes. The totes are cleaned at the beginning of each season and as needed throughout the season. Carts, wagons and the pick-up truck bed are swept clean or washed as needed before use.

Any tote used for storage of non-produce items (ex. Drip tape, ag-tyes ) will be thoroughly cleaned before being used as a harvest tote.

With the exception of berries, no produce is field packed. All berries for 3rd party sale will be packed...
It is, then, doubly ironic that by further centralizing are sickened – and perhaps some of them killed – in terroristic intentions, or at least the theoretical threat. At first just a source of amusement and, later, not that the impression that the language of regulators and consumer advocates seems frighteningly similar to that used by defense department and homeland security officials to talk about the threat of terrorism. At first just a source of amusement. The important word here is “systems” because that which handle, process or distribute food. What many people don’t realize today is that the new Food Safety Modernization Act (FSMA), which was signed into law in January of 2011, was intended primarily as an elaboration and ultimate completion of the BTA. For all the new about foodborne illness outbreaks since 2002, the new FSMA actually has its roots in the desire to thwart terrorist intentions, or at least the theoretical threat that some external evil force would attempt to destroy our nation by poisoning the food supply.

It’s ironic how FDA’s responses to food-related outbreaks of disease since the BTA have only proven just how vulnerable we have become. When we first hear of an outbreak, it is usually the case that people are sickened – and perhaps some of them killed – in 20 or 30 states before anyone even seemed to notice. It is, then, doubly ironic that by further centralizing the food system, FSMA’s prescribed actions will tend to make us even more vulnerable in that regard.

New Food Safety Regulations Miss the Point
Antibiotics and Pesticides and GMOs, Oh My! …or, It’s the System, Stupid!

by Brian Snyder, April 8, 2013, at writeofarm.com

In working on issues related to food safety over the past four years, I have often been struck by how the language of regulators and consumer advocates sounds frighteningly similar to that used by defense department and homeland security officials to talk about the threat of terrorism. It is the key to understanding both our greatest vulnerability and the solutions that would make our food more secure. If we continue to relentlessly focus on pathogens in food, and how they can be destroyed, we will miss altogether the nature of the systems that put them there in the first place. The problem really starts with unhealthy soil and lack of biodiversity on farms, and then is amplified by nationwide and global distribution networks built as though we wanted to control every single point of production. We should consider if they were looking too far outside the system for the biggest threats, or if the process of decay is instead happening mostly from within. And if you want to identify the true threat in the food system, look no further than the farmers and activists who continue to resist the real threats by advocating for wholesome food, produced with as few industrial inputs as possible, and served to customers they can actually talk to in the communities and geographical regions in which they reside.

The perimeter of the shed is regularly mowed and the building perimeter is checked to ensure that rodents or pests cannot gain access to the shed.

No glass containers are allowed in the vegetable washing area. All lighting above the work areas and storage areas is contained to prevent glass from falling in the event of breakage.

Storage Coolers

Storage cooler temperatures are checked and logged one time per day.

The link between the two sets of issues is in fact invidiable, starts with passage of the so-called Bioterrorism Act of 2002 (BTA) before the dust of the fallen World Trade Center in New York had fully settled. Among other things, the BTA for the first time required federal registration of all “critical facilities” that handle, process or distribute food. That category was supposed to exclude all farms, except that when the Food and Drug Administration (FDA) got to looking, they realized that in fact many farms these days are doing things that look like what they thought only food facilities would do. For historical perspective, farms have always been rather complex places of business, except perhaps in the minds of federal regulators.

What many people don’t realize today is that the new Food Safety Modernization Act (FSMA), which was signed into law in January of 2011, was intended primarily as an elaboration and ultimate completion of the BTA. So for all the new about foodborne illness outbreaks since 2002, the new FSMA actually has its roots in the desire to thwart terrorist intentions, or at least the theoretical threat that some external evil force would attempt to destroy our nation by poisoning the food supply.

It’s ironic how FDA’s responses to food-related outbreaks of disease since the BTA have only proven just how vulnerable we have become. When we first hear of an outbreak, it is usually the case that people are sickened – and perhaps some of them killed – in 20 or 30 states before anyone even seemed to notice. It is, then, doubly ironic that by further centralizing the food system, FSMA’s prescribed actions will tend to make us even more vulnerable in that regard.

House Packing Facility (Packing Shed)

All produce harvested on the farm goes through the packing shed for cleaning, inspection, and short term storage before being sold and shipped.

Receiving

Product delivered to the packing shed from the field is stored in the packing shed to protect it from contamination before washing and/or being placed into storage.

Washing/Packing Line

All water used in post harvest handling is potable. The well supplying the water is tested annually. Cleaning of the wash sinks and food contact surfaces is done at the beginning and end of each packing shed work shift.

Packing Shed Worker Health & Hygiene

A room adjacent to the packing shed contains employee lockers and a refrigerator for employee lunches and snacks. Eating is not permitted in the packing shed. All employees working in the packing shed need to wash their hands.

Packing Shed General Housekeeping

At the end of each harvest day, packing areas are dry swept and/or mopped. The washing, grading, sorting, and packing areas are cleaned. A thorough cleaning will happen on a weekly basis or as needed and this will be recorded on the Storage Cleaning Log. All culls and scraps from cleaning of produce are removed from the shed and placed in the cull pile before the end of each work shift.

Brian Snyder, Executive Director of PASA

Good sanitation and preventive measures through-out the food system make perfect sense, but so does the idea of ensuring locally and/or regionally focused mini-systems that would contain outbreaks that do occur to the greatest extent possible.

The important word here is “systems” because that is the key to understanding both our greatest vulnerability and the solutions that would make our food more secure. If we continue to relentlessly focus on pathogens in food, and how they can be destroyed, we will miss altogether the nature of the systems that put them there in the first place. The problem really starts with unhealthy soil and lack of biodiversity on farms, and then is amplified by nationwide and global distribution networks built as though we wanted to control every single point of production. We should consider if they were looking too far outside the system for the biggest threats, or if the process of decay is instead happening mostly from within. And if you want to identify the true threat in the food system, look no further than the farmers and activists who continue to resist the real threats by advocating for wholesome food, produced with as few industrial inputs as possible, and served to customers they can actually talk to in the communities and geographical regions in which they reside.

Maybe if the FDA did not so thoroughly miss the point about how all bad things come from systems that can be understood, engaged and altered for the better, we could be more optimistic right now about the new rules being promulgated. Instead, we will have to use every resource we can muster to defend the more sustainable food systems we have come to know and trust.
Impact of FDA’s Food Safety Regs on Farmers – and on the Food Movement

by Steve Gilman, NOFA-IC Policy Coordinator

Some History

The Food Safety Modernization Act is the first major food safety legislation passed by Congress since 1938’s Food, Drugs and Cosmetic Act, which set civil and criminal penalties for selling certain foods defined as adulterated. Thanks to a number of scandalous national food contamination outbreaks in the 1990s and early 2000s, some consumer groups and corporate produce processors associated pushed hard for new food safety regulations.

There had already been some legislative activity directed at farms in 2002 when Congress included food oversight in the ambiguously written and hastily passed Bioterrorism Act of 2002 that came as a response to the 9/11 terrorist attacks. Most worrisome, the act included statutory language that reduced a list of standard harvesting operations as processing activities — reclassifying some farms as facilities and requiring farmers to register annually with FDA, comply with increased standards, keep records and maintain pasture. Although the Bioterrorism Act was not strictly enforced it is still on the books — and it directly informs a number of FDA’s proposed FSMA rules.

Under pressure from some consumer groups and produce associations, in 2009 a food safety bill originated in the agribusiness-friendly House Agricultural Committee. The proposed one-size-fits-all provisions in the House bill took the Bioterrorism Act rules several severe steps further. Seeing the writing on the wall, many organic and sustainable agriculture groups and individual farmers from all around the country came together under the auspices (and Capitol Hill expertise) of the National Sustainable Agriculture Coalition (NSAC) to organize a concerted political response.

The next stage was in the Senate where, thankfully, NSAC had already built good long-term relationships. They were able to enlist a number of Senators to support Amendments protecting family farmers, helping to reverse some of the excesses of the Bioterrorism Act. This turned into a policy fight every step of the way, with an opposition led by Big Produce organizations and the consumer group, the Center for Science in the Public Interest (CSPI), which was adept at working behind the scenes to thwart the farmer protections. In a final battle an Amendment by Senator (and organic farmer) Jon Tester of Montana was finally approved, providing an Amendment by Senator (and organic farmer) Jon Tester of Montana was finally approved, providing alternative oversight provisions and exemptions from the federal rules for certain smaller scale fam-

il farmers.

After horse-trading aligning the House and Senate versions, the Food Safety Modernization Act was finally passed at the 11th hour in late 2010 — ending a two year route through Congress. The next day, FDA released its rule-writing phase, where FDA staff worked with consultants to translate the intent and particulars of the statute into on-the-ground regulations. Some 1200 pages thick, the proposed rules were not released for public comment until after the November 2012 elections to keep them from becoming an issue in the campaigns. In January, 2013 FDA issued their Produce Rule (for farmers) and Preventive Controls Rule (for facilities) for public comment. Initially the comment period was due to expire in mid-May — but due to a public outcry over the complexity of the documents it was recently extended until September 16th.

Farmers Bearing the Brunt

The regulations cover everything about how farmers farm including: biological soil amendments, water, on-farm processing, worker health, domestic and wild animals, tools, equipment and buildings. Initial analysis by the Task Force, together with assistance from outside economists, microbiologists, law clinics and other specialists shows these proposed regulations will have a definite impact on family farmers — and thereby on the food movement as well. According to recent economic studies farmer compliance costs to upgrade buildings, buy equip,

ment, maintain records, conduct tests, etc. could easily reach into the $20,000+ range per farm. But since FDA has no overall impact studies many other costs may remain hidden until farmers are required to comply with them.

Further, under the proposed rules, it’s the farmer who is often left holding the bag for contamination produced by other entities. If a CAFO moves in next door, it’s the produce farmer who must put in buffers and site crops out of range of any water or windborne pollution. And while the periodic testing of irrigation sources might be a good practice, in re-

ality the farmer is the one who pays for the tests and must bear the economic losses from any contamination problem.

There’s a lengthening list of provisions that need to be completely rewritten. Even basic definitions delineating “farms” and “facilities” are murky and conflicting. Farms can suddenly find themselves classified as facilities. Although there are size exemptions, produce farmers who also grow non-regulated “food items” such as hay get their total farms sales counted, which can easily push them out of an exempted category. Items covered in the Produce rule are not treated consistently with their counterparts in the Preventive Controls rule. When items such as these are pointed out in meetings, con-

ference calls and webinars with FDA, the officials are sometimes at a loss how to answer them and the questioners are generally instructed to make formal written comments depicting the problems — as well as providing the exact language necessary to fix them.

The most egregious override of Congressional in-
tent is an open-ended, vaguely phrased “material conditions” clause that gives FDA full powers to withdraw a farm’s statute-authorized exemptions. Slipped into FSMA at the last moment by CSPI and others, there are no mandated protocols, compli-

ance timeframes or evidence requirements — while the burden of proof is placed completely on the ac-
cused farmer. Although a farmer may appeal such a ruling (to FDA, not an outside authority) there’s no depiction of what records can stand in as acceptable evidence when the farm was exempt from record-

keeping to begin with. Further, there’s absolutely no provision enabling a farmer to reinstate his or her exemption once the purported material conditions have been addressed — or FDA cannot show there is a problem. And beyond FDA’s direct action powers against single farms there’s no language prevent-

ing them from conducting a blanket withdrawal of exemptions from a large number of farms that they deem are engaged in some sort of category of risky production.

A Necessary Evil?

As one of the more outspoken advocates for severe-
ly limiting the FSMA-mandated farmer exemptions, CSPI focused on recommending that additional regulations, fees and paperwork are a “necessary evil” needed to combat the risks and burdens of food contamination in the marketplace and they are working hard behind the scenes to make this a reality. At the same time they publicly advocate the values of organic and sustainable farms and have created an annual na-
tional Food Day (October 24th) touting these values — even when a United Nations World Food Day (on October 16th) has been in existence since 1945.

Both Congress (in formulating FSMA) and FDA (in rule-making), however, recognized that creating one-size-fits-all regulations applied to all scales of farming and to all regions of the country is not only unfair, but futile. Due to the tremendous variability of conditions (a citrus grower in Florida deals with much different conditions than a potato grower in Minnesota, for instance) these proposed regs neces-

sarily allow for considerable producer discretion and interpretation. And since there is scant science to back up more specific metrics, FDA will be fol-

lowing up the FSMA regs with a series of ongoing Guidelines, which will also be subject to grower oversight and comment periods.

As we’ve seen time and time again, a strict regula-
tory approach to a desired goal is often counter-
productive. Sometimes all that is really created is a lot of extra paperwork — and bigger bureaucracies to process it all.

While these proposed rules directly affect farmers, everyone who is part of the Food Movement has a stake in the outcome. Farmers are fully involved in farming and have scarce time to participate in the comment process. That’s where the Food Movement needs to step in. There’s a wide range of good food organizations and concerned citizens who have the resources and expertise to engage in this process.

The future of the food movement depends on it.

For regularly updated comment guidance on the FDA’s proposed regulations based on FSMA please go to: <http://sustainableagriculture.net/fsma/>
The Natural Farmer
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Betsy A. Bihn, Ph. D.

Making Sense of Produce Safety

Right about now several people reading this article are thinking or saying: “I have never made anyone sick.” Well, my response to that is: “Prove it!” Several years ago I had the opportunity, or maybe I should say misfortune, to be part of a foodborne illness outbreak. Yes, I work in food safety so I have lots of friends and family found this fact to be downright amusing. One of the interesting parts of this story is that I didn’t get very sick. I had a foodborne illness. I thought I had the flu. Had I not been at a meeting with other researchers and farmers that I do not normally see on a day-to-day basis, I would not have been there. I would not have vomited for a full day and then slowly recovered for a week as my body experienced the feeling of being beaten with a baseball bat. There is no chance I would have gone to the doctor or submitted a fecal (poop) sample. As it turns out though, everyone else who was sick was kind enough to email me and let me know. It did not take long to realize that we all were part of a foodborne illness outbreak, most likely caused by our catered lunch and a food handler who apparently did not find hand washing to be a big priority.

Another interesting fact is that we did not get sick until almost three days after we had eaten the contaminated food. So for the sake of argument for those who claim they have never made anyone sick, how do they know? Listeria monocytogenes, the pathogen responsible for sicking L147 and killing 33 after consuming cantaloupes grown in Colorado in 2011, has a varying incubation period of between 3 days and 3 months. If a grower sells fresh produce at a farmer’s market or on Saturday to 100 different families who do not know each other, who do not get sick for several days, and who, despite getting sick, do not go to the doctor’s office or submit fecal samples, how do they know that their illness was ever shown on the monitoring systems we have in place? They would not; it is just that simple. So, I am fine with growers telling me: “I am unaware of ever making anyone sick” or “Illnesses have never been traced back to produce I have grown”, but it is harder for me to accept “I have never made anyone sick” because there is simply no way to know if this is true.

Growers often tell me “My family eats this food, why would I do anything that puts it at risk?” This is a good point but without basic produce safety knowledge, risky things can be done unintentionally that result in contamination. Nothing, and I mean nothing, in life is 100% safe but when outbreaks happen and there were things that could have been avoided had people understood a little bit about microbiology and produce safety risks, it makes me think we all need to do a little better. Scientists and educators need to make information more available and provide opportunities for farmers to learn about risks and how they can reduce them. Farmers need to believe produce safety is important and that they can impact safety through the practices they use on their farms. Will this remove all risks? No. Will it reduce risks and make things safer for everyone? Yes.

Other Reasons a Farmer Might Consider Produce Safety

Aside from simply wanting to grow and distribute the safest produce possible and run a successful farm, there are two other reasons that can be motivating forces to start thinking about produce safety. The first is meeting buyer requirements. Some buyers require that food safety practices be in place on a farm or they will not buy product from the farm. What buyers require varies. It can be as simple as reviewing a farm’s food safety plan or as intensive as passing a complicated third party audit. Buyer food safety requirements often motivate growers to learn about produce safety and implement practices because they need access to these markets for their crops. Buyer demand and the consistency of their requirements from year to year can be highly variable which can be quite frustrating, but meeting their demands is important if growers want their business.

The second, more recent motivating force was the birth of the proposed Produce Rule that is part of the Food Safety Modernization Act. Please understand the current Produce Rule is proposed, not final, so the requirements as written are not enforceable on yet complete. In fact, growers now have the opportunity to comment on what is contained in the proposed Produce Rule and provide feedback as to how the proposed regulations might impact their farm or how the language might be changed to make the provisions better. This is very important and in the recommendations below the procedure for commenting on the proposed regulation is outlined in detail. The key to mentioning the proposed Produce Rule in this section is to point out that many growers will be subject to this regulation when it is final, so it serves as a motivating force to learn about produce safety and implement practices. It is important that many small farms will be exempted from the regulation, but right now there are a few provisions that are likely to include even small plot farmers.

One question that comes up often in trainings is “If I comply with the regulation, will buyers accept that instead of an audit or will their requirements be the same as the regulation?” The answer is most likely “no” to both sections of that question. Buyers can demand whatever they want or whatever the market will bear. Most audits currently in use go beyond the requirements outlined in the proposed regulation. It seems likely the regulation will set the floor or the foundation for produce safety requirements, but for buyer requirements, the sky is the limit. The good news here is that if a farm has passed a third party audit, it is likely they are already doing most of the things that will be required in the regulation. The opposite though is likely not the case.

Recommendations for Growers

Looking at the current produce safety landscape with variable buyer requirements, a proposed produce regulation, and most small farm operations already busy with growing and selling produce, here are a few things that every farmer should do in regards to produce safety.

1. Learn about produce safety.

There are lots of educators who like to say produce safety practices are common sense. I disagree. The way some of the microbial pathogens behave, the low infective dose that makes people sick, the things that increase risks on the farm, and lots of other things are not common things you might have learned from your farming parents. Most horticulture or agronomy departments across the US do not offer produce safety course work and if they do, it is a relatively new class. This means most of our current farmers who are over the age of 55 never took a course in produce safety or microbiology but now they need to know at least a little of this information to make informed decisions. The good news is that most farmers I have met are smart, resourceful people, capable of learning new things. So, the bigger issue is convincing them they need to know it. Farmers tend to be a stubborn lot, so they will only seek out information they think they need to know.

2. Evaluate your own operation with produce safety in mind.

Every farm is different, so each farmer needs to assess the risks on their own farm. Every farmer I have ever asked: “what is your biggest produce safety concern?” has given me an answer. It might be the quality of the water they use in their overhead irrigation system, it might be workers who leave...
dirty toilet paper piled in the corner instead of putting it in the toilet, or it might be a wildlife issue they are having a tough time controlling. Regardless of what it is, they have a response. I find the responses sometimes change once they learn more, but the key point is that no one knows the farm better than the farmer.

3. Write a food safety plan for the farm (even if it is only a page or two).
In my experience, growers make the most produce safety progress when they write a few things down, even if it is only a short list of the things that concern them. Real progress starts when thoughts hit paper or an iPad (for all you tech savvy farmers). Borrowing from the basics of chemical reactions, this process is depicted in Figure 1. Write it down to make it real and get moving. Once you start, you can add to it and make it look pretty, but most importantly write something down since it will get you going in the right direction.

4. Use the resources that are available.
There are lots of resources available to help growers understand and implement produce safety practices. The National GAPs Program (www.gaps.cornell.edu) and the Produce Safety Alliance (www.producesafetyalliance.cornell.edu) both have educational resources but also have links to produce safety programs from across the country. The University of California, Davis, Rutgers, the University of Minnesota, the University of Florida, Penn State University, Texas A&M, and many other land-grant institutions have programs that provide information and resources. There are template record keeping logs, template food safety plans, training videos, posters, and many other educational materials available for free or for little cost. There are even online produce safety courses if growers are having a hard time finding training opportunities close to home. There are template record keeping logs, template food safety plans, training videos, posters, and many other educational materials available for free or for little cost. There are even online produce safety courses if growers are having a hard time finding training opportunities close to home. The important point is that resources and help are available now, so growers should use all these assets at their disposal.

5. Do things that reduce risks.
The end goal of all this encouragement and all the resources is to make fresh produce as safe as possible. Once growers have gained produce safety knowledge, assessed their risks, and collected the necessary resources, the final step is to put practices into place. There is significant concern about costs associated with produce safety practices. It is true that some things can be very expensive, such as replacing an old wooden packing line with a stainless steel one, but improvements and modifications like this are not necessarily required. Things such as training workers, providing toilets and hand washing sinks, and keeping packing areas organized are not expensive, but can reduce food safety risks on the farm. The biggest investment is usually time including the time to think about produce safety and put practices in place. The thing to keep in mind is no one does everything at once. Address the biggest food safety concerns first and think strategically about how practices will fit into your current operation.

6. Read the proposed Produce Rule, understand how it might affect you, and submit comments for the things that do not look right or that concern you.
The first ever proposed regulation for fresh produce deserves the attention of growers who produce fresh fruits and vegetables. It may seem absurd, it may be frustrating, but it is not going away. The best thing a grower can do is engage in the process so they know what is proposed and how it might affect them. Right now growers have a chance to speak their mind by commenting on the proposed rule. The best comments include details about why something is good, bad, workable, or absurd and how it might be changed to make it better. American growers produce a huge diversity of fruits and vegetables using many different practices. It is foolish to think that those who wrote the proposed rule understand all crops, all regions, or all farming practices. This is not a criticism of the authors of the proposed rule. It is just a simple fact. Having conducted a series of question and answer teleconferences with the FDA, it is clear to me that they are interested in receiving comments that help them understand and edit the proposed rule so that it reduces risks on fresh produce farms without negatively impacting farming operations. Now is the time to be involved and be heard. Comments can be submitted through the FDA website now through September 16, 2013 at http://www.regulations.gov/?s=FDA-2011-N-0921-0001. To listen to the recordings of all of the FDA question and answer teleconferences that discussed the proposed Produce Rule section by section, visit the Produce Safety Alliance at www.producesafetyalliance.cornell.edu

Well, if you have made it all the way through this article, I would like to thank you for your attention and consideration. Produce safety is a lot to take in if this is the first or even second time you have thought about it. Stay calm and try not to panic or get so frustrated it takes years off your life. Talk to your fellow farmers, seek out resources, get started, and never underestimate the value of taking a step back to clear your mind or enjoy an adult beverage.

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Final Suggestions for Your Comments to FDA

From the National Sustainable Agriculture Coalition

Here are some general guidelines to help your comment have its maximum impact:

• Your story matters – be sure to share with FDA why this matters. Who are you? Are you a farmer? Share how the rules might impact your farm. Are you a consumer? Make sure FDA knows the kind of food you like to buy from farmers and that you want to ensure these rules don’t unfairly burden those farmers.

• Keep the tone polite – remember that all comments will become part of the public record and will be read by FDA officials.

• Make sure you have a clear “ask” for FDA – either about a specific issue or broadly, about the importance of ensuring both safe food and thriving family farms.

• Do not exactly copy someone else’s comment – for FDA to count your comment, it must be unique. You can make the same or similar points as another person, but you do need to add your own perspective as much as possible.

From the New England Farmers Union:

1. FDA has seriously underestimated the costs of compliance with these rules. Costs to farmers will be significant and will threaten the viability of many New England specialty crop producers. Our early analysis suggests that compliance with the agricultural water component alone will cost New England farmers relying on river or pond sources for irrigation, $13-15,000 per year.

2. The rules threaten the development of food hubs and other aggregation, distribution structures that are a fast growing part of the local and regional food system. Farms or farm facilities that aggregate or offer for sale products of other farms will be subject to the more stringent and more expensive preventive control rules. Food hubs enable small farms to capture economies of scale, access institutional and wholesale markets, and meet the growing demand for produce from small and mid-size, local farms. USDA and the private sector have made significant investments in assisting farmers in developing value added products, food hubs and cooperative marketing. The proposed rule does not define a food hub, and it does not provide clear guidance for the many types of legal structures, ownership models, producer contracts, activities, end users, and settings to be found among food hubs. FDA must clarify these issues and create group compliance standards for food hubs and other aggregators such as producer co-ops and multi-farm CSAs. Without group compliance opportunities, the cost of operating these structures will become too high, and small and mid-scale farms will lose market opportunities.

3. The exemptions and alternative compliance measures for small farms that primarily market direct to consumers, co-ops and restaurants under the Food Safety Modernization Act are contracted under the rules. The rule allows FDA to withdraw the qualified exemption without specifying what conduct or criteria they will use to for withdrawal.
New Food Safety Rules Would Cost Small Farms $13,000

Draft Regulations Open to Public Comment Until Sep. 16

The Food Safety Modernization Act, passed by Congress in 2011 after several fatal outbreaks of food borne diseases, creates new rules on American farms. The FDA in January issued draft regulations to implement the law and estimates that meeting them will cost small farms an average of $13,000 and very small farms an average of $4,700.

The regulations are open for public comment until Sep. 16, 2013. This issue contains a number of articles explaining them, how farmers and consumers supporting a local food system are reacting to them, and how to register your comments on them.

Packing rooms, like this shed on Andy Fellenz’ New York farm, are one of the areas where new regulations will govern water quality, worker sanitation, exclusion of wildlife, and washable surfaces.

This newspaper contains news and features about food and farming in the Northeastern US as well as a Special Supplement on Food Safety on the Farm.