The Food Safety Modernization Act’s Produce Safety Rule

Theresa Mary Jarvis Long

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Dr. Laura K. Strawn, Department of Food Science and Technology
Dr. Joseph D. Eifert, Department of Food Science and Technology
Dr. Steven Rideout, Department of Plant Pathology and Weed Science

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ABSTRACT

Limited resources are available for extension personnel to distribute to stakeholders seeking information on the Food and Drug Administration’s Food Safety Modernization Act (FSMA) and its seven different rules: Produce Safety Rule, Preventive Controls for Human Food Rule, Preventative Controls for Animal Food Rule, Foreign Supplier Verification Program for Importers of Food for Humans and Animals, Accredited Third-Party Certification Rule, Focused Mitigation Strategies to Protect Food Against Intentional Adulteration Rule, and Sanitary Transportation of Human and Animal Food Rule. Of the seven different rules associated with FSMA, the Produce Safety Rule (PSR) will evoke the most changes of stakeholders. The PSR is the first time the produce industry will be required to meet specific food safety standards. Therefore, this project constructed four educational publications focused on providing an overview of FSMA’s PSR and also the key components (including worker training, health and hygiene; domestic and wild animals; and agricultural water). The publications were developed to be resources for both extension personnel and the produce stakeholders they serve. Additionally, these educational publications were distributed to Virginia Cooperative Extension (VCE) agents for evaluation on their usefulness. The majority of VCE agents who reviewed the material responded that the publications were appropriate, useful and served their needs. It is recommended that future publications (e.g., biological soil amendments, equipment/tool/building sanitation) be developed to address other key components of the PSR not covered under this project.
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Introduction

Background and Setting

The Food and Drug Administration’s Food Safety Modernization Act (FSMA) is federal legislation that was passed by Congress and signed into law on January 4, 2011. FSMA is the first major overhaul to the United States’ food system since the Food, Drug, and Cosmetic Act of 1938. The goal of FSMA is to strengthen the food system by developing food safety standards (or best practices) and shifting the focus to a prevention-based food safety culture. FSMA is constructed of seven different rules including the Produce Safety Rule, Preventive Controls for Human Food Rule, Preventative Controls for Animal Food Rule, Foreign Supplier Verification Program for Importers of Food for Humans and Animals, Accredited Third-Party Certification Rule, Focused Mitigation Strategies to Protect Food Against Intentional Adulteration Rule, and Sanitary Transportation of Human and Animal Food Rule. Thus, FSMA will construct an “integrated national food safety system” (USFDA Background on FSMA) as each of the seven different rules aims to develop a safer, more robust food safety system.

As of November 27, 2015, the FSMA Produce Safety Rule (PSR) has been published in the Federal Register and compliance dates range from 2017 to 2021 (citation 80 FR 74353). The PSR sets a series of science-based standards for the safe growing, harvesting, packing, and holding of produce grown for human consumption. Similar to other FSMA rules, the PSR aims to be proactive rather than reactive by focusing on high risk practices and identification of hazards within individual operations. The PSR applies to most produce in its natural, raw and unprocessed state (see Appendix A). The PSR does not apply to processed products, produce grown for personal use or on-farm consumption, produce that is "rarely consumed raw,” food grains, farms that make less than $25,000 in all produce sales in a 3 year average (see Appendix B). There is another exemption that farms may fall under as long as both of the following requirements are met (Tester-Hagan Amendment) which is farms that make less than $500,000 in all food sales in a 3 year average and at least 50.1% of all food sales are direct to qualified end users. A qualified
end user is either a consumer or a restaurant/retail food establishment in the same state/Indian reservation or within 275 miles of where the produce was grown. This requirement must also be met historically for the previous three years of the farm’s operations. A farm with a qualified exemption (i.e. Tester Hagan Amendment) must still meet certain modified requirements (citation 80 FR 74353). The PSR sets a series of standards for agriculture water; biological soil amendments; spouts; domestic and wild animals; worker training, health and hygiene; and equipment, tools, and buildings. These standards will hopefully minimize the risk of produce contamination and thus reduce the number of produce associated illnesses.

**Statement of the Problem**

Agriculture is Virginia’s largest industry with an economic impact of over $55 billion and provides the Commonwealth with 357,100 jobs (VDH, 2014). Many of Virginia’s agricultural commodities rank in the top ten when ranked against all other states within the United States. This demonstrates the impact that Virginia’s agriculture has not only within the Commonwealth but also among other states. According to the National Agricultural Statistics Service (NASS), Virginia sold over $92 million dollars of vegetables, melons, potatoes, and sweet potatoes in 2012 (USDA, 2009).

The continued economic success of fresh vegetable production in Virginia is dependent on maintaining robust food safety. Food safety on the farm influences the food system from planting to harvesting. Virginia Cooperative Extension’s (VCE) mission is to provide information, education and tools for the public to use to improve their business or life. In the VCE system, there is no information available (e.g., publications) on FSMA and the associated standards stakeholders may need to meet. Currently, in order to obtain information about FSMA or its different rules (e.g., Produce Safety Rule), stakeholders must use the FDA website, the Produce Safety Alliance website, or other land-grant university extension resources.
Purpose of the Project

The purpose of the project is to establish a series of publications for Virginia Cooperative Extension agents to use for their programming needs throughout the Commonwealth.

Project Objectives

1. Create and publish a series of publications on the Food Safety Modernization Act’s Produce Safety Rule to be made available in the Virginia Cooperative Extension system.

2. Improve vegetable growers’ understanding of the Food Safety Modernization Act’s Produce Safety Rule as it pertains to their individual operations by widespread dispersal of the publication series.

Definition of Terms

1. Exemption- Disqualified from or free from the regulations imposed by the Produce Safety Rule.

2. Federal Register – The official record book of the federal government of the United States. It contains all government agency rules, proposed rules, and any public notices. The Food Safety Modernization Act and the Produce Safety Rule are officially published in the Federal Register. Any references or citations to the Federal Register will be coded as follows: ## FR ####.

3. Food Safety Modernization Act (FSMA) - Federal legislation passed by Congress (signed into law in 2011). FSMA is the first major overhaul of food safety in the United States since the Food, Drug, and Cosmetic Act of 1938. FSMA lays the framework for preventing contamination events, rather than responding to contamination events in the food system.

4. Good Agricultural Practices (GAPs) – A set of best management practices for the production of fresh fruits and vegetables. When correctly used and put in place, GAPs are intended to minimize the risk of microbial food safety hazards.
5. *Produce Safety Rule (PSR)* – The rule is a collection of science-based standards for the growing, packing, harvesting and storing practices of produce grown for human consumption. The final rule is a collection of the original rule and all the subsequent revisions, amendments and modifications (supplemental rule).

6. *Virginia Cooperative Extension (VCE)* – A network of educational outreach professionals that provide the Commonwealth of Virginia residents with resources in the areas of Agriculture and Natural Resources (ANR), Family and Consumer Sciences (FCS), Community Viability, and 4-H Youth Development. Since 1914 and the passage of the Smith-Lever Act, Virginia Tech and Virginia State University have served as VCE.

*Review of the Literature*

“Over the last several years, the detection of outbreaks of foodborne illness associated with both domestic and imported fresh fruits and vegetables has increased” (USDA, 2012). The increased number of outbreaks comes even though Americans have access to one of the safest food markets in the world. “Approximately 13% of reported food-borne outbreaks were linked to produce from 1990 to 2005” (Doyle, M. P, et al.). Some of the most recent and most impactful foodborne illness outbreaks have occurred within the last two decades. In 2006, spinach was contaminated during the preharvest process and linked to the strain of *E. coli* O157:H7. This was one of the first major preharvest outbreaks reported after a nationwide outbreak traced to bagged spinach from California. A Center for Disease Control and Prevention investigation returned the cause of contamination as potentially feral swine, cattle, and surface water contamination (CDC). In 2008, another outbreak was traced back to the pre-harvest environment; a *Salmonella* Saintpaul associated with jalapeno peppers sickened 1,500 individuals across 43 US states and Canada. After investigation, it was identified that the pre-harvest agricultural water source used for irrigation was the carrier for the foodborne pathogen implicated in the outbreak (Mody, R. K. et al.). In 2011, an *L. monocytogenes* outbreak was associated with cantaloupe and resulted in 147
illnesses, 33 deaths, and one miscarriage in 28 states. It is important to note that this outbreak was traced back to the packinghouse; however, they could not rule out contamination being introduced into the packinghouse from the field (McCollum, J.T. et al.). Another example of post-harvest contamination of fresh produce was a *Salmonella* outbreak associated with cantaloupe from a farm in Indiana. This salmonellosis outbreak caused 261 illnesses and three deaths in 24 states. It was determined that equipment design and the packing/holding times were some conditions that may have contributed to the outbreak (USFDA, 2013). Recently, less than two years ago, a *Salmonella* Newport outbreak linked to cucumbers occurred in August 2014. Between May and September of 2014, 275 patients in 29 states were identified with illnesses that were determined to be caused by *Salmonella* Newport that had previously been identified on the Eastern Shore of Virginia in tomatoes in 2002. Previous tomato-borne outbreaks have occurred in 2002, 2005, 2006 and 2007 affecting a total of 585 persons. After investigation by the FDA and the USDA of the 2014 *Salmonella* Newport outbreak, it was determined the cucumbers were allegedly contaminated in the pre-harvest environment by application of poultry litter. The litter was not available for testing, so a definitive result was unable to be substantiated (Angelo, K. M. et al.).

Due to foodborne outbreaks, the FDA and the USDA have been working together to create a set of industry standards for the agricultural industry in order to reduce contamination events in the pre- and post-harvest environments. These industry standards would be a set of best management practices that, if placed into practice, would “effectively serve to reduce microbial hazards” (VDH, 2014). In 1998, the FDA and the USDA issued “Guidance for Industry – Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.” This guide was the basis for development of the Produce Safety Rule, the Good Agricultural Practices program and the best management practices that the agricultural industry follows for the production of most fresh fruits and vegetables. Within the “Guidance for Industry”, growers are able to find voluntary practices to potentially reduce the risk of microbial contamination while growing,
harvesting, packing, and holding fresh fruits and vegetables. The potential for $92 million of fresh produce sales in Virginia to be associated with a foodborne illness/contamination event is too great (USDA, 2012). Thus, adhering to a GAPs program and/or participating in best management practices, even though voluntary, will reduce the risk to growers exponentially.

Project Overview

Targeted Population and Participating Audience

The target population for this project is VCE county agents and specialists. Publications in the hands of county agents and specialists are circulated to clientele who will benefit from the production of VCE publications on the FSMA PSR. In particular, fresh produce growers, processors, packers, and Virginia start-ups will be looking for information. Due to the variety of ways to publicize and share the information through the VCE system, the audience that can be impacted by this information may be considerable in size.

Methodology

Four publications were written to address the primary areas that agents and specialists get queries on related to the FSMA PSR. The first publication focuses on the Food Safety Modernization Act’s Produce Safety Rule and its background (see Appendix D). Publications two through four are written on three of the six identified routes of microbial contamination: agricultural water (see Appendix E), domestic and wild animals (see Appendix F) and worker training, health and hygiene (see Appendix G). The latter publications (Appendix E, F and G) describe the minimum standards set by FSMA PSR in fact sheet form (with regulatory language removed for ease of understanding and reading).

These publications were also distributed electronically to 15 Virginia extension agents that have expressed interest in food safety and who serve high acreage production areas. Each agent was surveyed to determine the usefulness, appropriateness, and benefit of material for their population using a Likert scale.
Summary of Outcomes, Discussion and Recommendations

Program Outcomes

Survey results were received from 7 of the 15 agents for a 46% response rate. Of those surveyed, 85% strongly agreed and 15% agreed that the material was useful and appropriate for their population. Of those surveyed and responded, 71% strongly agreed and 29% agreed that this material would be of benefit to their population.

Implications and Recommendations

VCE agents surveyed overwhelmingly agreed that the publications produced by this project were of benefit to their populations and were written appropriately. In addition the majority of those who responded felt these publications would assist them in educating their targeted population. Additionally, these publications can assist extension agents and others to be able to quickly and easily disseminate information on FSMA PSR compliance.

The evaluation of these publications, as done in this project, was limited in scope and sample size. These publications should be evaluated further and include other jurisdictions throughout the Commonwealth. As the response was positive, it was also recommended that the FSMA series of publications be completed. Other topics that should be addressed in the future are biological soil amendments; sprouts; and equipment, tools and buildings. Lastly, these publications should be very useful to stakeholders (e.g., growers) in the Commonwealth of Virginia as they remove regulatory language and provide the FSMA PSR standards in a simple, easy-to-read format.
References


Appendices

Appendix A

§112.1 - What Food is covered by this part?

(a) Unless it is excluded from this part under §112.2, food that is produce within the meaning of this part and that is a raw agricultural commodity (RAC) is covered by this part. This includes a produce RAC that is grown domestically and a produce RAC that will be imported or offered for import in any state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(b) For the purpose of the part and subject to the exemptions and qualified exemptions therein, covered produce includes all of the following:

(1) fruits and vegetables such as almonds, apples, apricots, apriums, artichokes–globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussel sprouts, burdock, cabbages, Chinese cabbages (Bok choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops) citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruits), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini, sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams.

(2) Mixes of intact fruits and vegetables (such as fruit baskets).

Citation 80 FR 74548
Appendix B

§112.2 - What produce is not covered by this part?

(a) The following produce is not covered by this part:

(1) Produce that is rarely consumed raw, specifically the produce on the following exhaustive list: asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

(2) Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management; and

(3) Produce that is not a raw agricultural commodity.

(b) Produce is eligible for exemption from the requirements of this part (except as noted in paragraphs (b)(1), (2), and (3) of this section) under the following conditions:

(1) The produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of part 113, 114, or 120 of this chapter, treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products; and

(2) You must disclose in documents accompanying the produce, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and

(3) You must either:

(i) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from the customer that performs the commercial processing described in paragraph (b)(1) of this section that the customer has established and is following procedures (identified in the written assurance) that adequately reduce the presence of microorganisms of public health significance; or

(ii) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from your customer that an entity in the distribution chain subsequent to the customer will perform commercial processing described in paragraph (b)(1) of this section and that the customer:

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and
(B) Will only sell to another entity that agrees, in writing, it will either:

(1) Follow procedures (identified in a written assurance) that adequately reduce the presence of microorganisms of public health significance; or

(2) Obtain a similar written assurance from its customer that the produce will receive commercial processing described in paragraph (b)(1) of this section, and that there will be disclosure in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and

(3) You must establish and maintain documentation of your compliance with applicable requirements in paragraphs (b)(2) and (3) in accordance with the requirements of subpart O of this part, including:

(i) Documents containing disclosures required under paragraph (b)(2) of this section; and
(ii) Annual written assurances obtained from customers required under paragraph (b)(3) of this section; and

(5) The requirements of this subpart and subpart Q of this part apply to such produce; and

(6) An entity that provides a written assurance under § 112.2(b) (3) (i) or (ii) must act consistently with the assurance and document its actions taken to satisfy the written assurance.

Citation 80 FR 74549
Appendix C

STANDARDS FOR PRODUCE SAFETY
Coverage and Exemptions/Exclusions for Proposed 21 PART 112

The Preventive Controls for Human Food rule clarified the definition of a farm to cover two types of farm operations, primary production farms and secondary activities farms. The same definition is used in the Produce Safety rule (section 112.3(c)). Below are basic criteria that determine whether an operation that meets the definition of "farm" is subject to the produce rule.

Does your farm grow, harvest, pack or hold produce?
Sections 112.1 and 112.3(c)

NO
Your farm is NOT covered by this rule.

YES

Does your farm on average (in the previous three years) have <$25k or less in annual produce sales?
Section 112.4(a)

NO

Yes
Your farm is NOT covered by this rule.

YES

Is your produce one of the commodities that FDA has identified as rarely consumed raw?
Section 112.2(b)(1)

NO

Yes
This product is NOT covered by this rule.

YES

Is your produce for personal/on-farm consumption?
Section 112.2(d)(2)

NO

Yes
This produce is eligible for exemption from the rule.

YES

Is your produce intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a "kill step")?
Section 112.25(b)

NO

Yes
This produce is NOT covered by this rule.

YES

Does your farm on average (in the previous three years) as per Section 112.5, have <$500k annual food sales, AND a majority of the food (by value) sold directly to "qualified end-users"?
Section 112.3(c)

"Qualified End-User" as defined in Section 112.2(c) means:

- the consumer of the food OR
- a restaurant or retail food establishment that is located—
  (i) in the same State or the same Indian reservation as the farm that produced the food, OR
  (ii) not more than 275 miles from such farm.

The term "consumer" does not include a business.

NO

YES

Your farm is eligible for a qualified exemption from this rule, which means that you must comply with certain recordkeeping requirements and keep certain documentation, as per Sections 112.6 and 112.7.

YOU ARE COVERED BY THIS RULE.
Food Safety Modernization Act - Produce Safety Rule

Theresa Long1, Rachel Pf stock2, Laura Strawn1

1Graduate student, Agriculture and Life Sciences; 2Research Specialist, Food Science & Technology; 3Extension Specialist, Food Science & Technology

What is the Food Safety Modernization Act (FSMA)?
The Food and Drug Administration (FDA)’s Food Safety Modernization Act (FSMA) is federal legislation, passed by Congress and signed into law on January 4, 2011. It is the largest change to our nation’s food safety system since the Food, Drug, and Cosmetic Act in 1938. FSMA specifically focuses on preventing foodborne illness rather than reacting to illnesses after they occur. FSMA aims to construct an integrated food safety system and is made up of seven different rules.

These rules include:
- Produce Safety Rule (PSR)
- Preventive Controls for Human Food Rule
- Preventive Controls for Animal Food Rule
- Foreign Supplier Verification Program For Importers of Food for Humans and Animals
- Accredited Third-Party Certification Rule
- Focused Mitigation Strategies to Protect Food Against Intentional Adulteration Rule
- Sanitary Transportation of Human and Animal Food Rule

Each of the different rules aims to develop a safer, more robust food safety system. For example, the Foreign Supplier Verification Program for Importers of Food for Humans and Animals Rule will ensure that imported foods are held to the same safety standards as domestic foods. Here we give an overview of the Produce Safety Rule.

FSMA Produce Food Safety Final Rule

The Produce Safety rule (PSR) is one of the seven food safety regulations that are part of the Food Safety Modernization Act (FSMA). As of November 27, 2015 the PSR has been published in the Federal Register (citation 80 FR 74353). The PSR sets a series of science-based standards for the safe growing, harvesting, packing, and holding of produce grown for human consumption. Similar to other FSMA rules, the PSR aims to be proactive rather than reactive by focusing on high risk practices and identification of hazards within individual operations.

Within the PSR, six specific identified routes of potential microbial contamination are identified and minimum standards for the safe growing, handling, packing and storing of produce have been set. The PSR sets standards for:
1. agricultural water
2. biological soil amendments
3. sprouts
4. domesticated and wild animals
5. worker training and health and hygiene
6. equipment, tools, and buildings

The PSR proposes minimum farm-operation standards to protect public health and safety in a prevention-based method.

Exemptions

The PSR applies to most produce in its natural, raw and unprocessed state. The Rule does not apply to:
- processed products (e.g. tomatoes for paste)
- produce grown for personal use or on-farm consumption
- produce that is “rarely consumed raw” (e.g. potatoes)
- food grains (e.g. barley)
- farms that make less than $25,000 in all produce sales; in a 3 year average

There is another exemption that farms may fall under, as long as the farm meets BOTH the following requirements (Testor-Hagan Amendment):
- farms that make less than $500,000 in all food sales; in a 3 year average
- At least 50.1% of all food sales are direct to qualified end users. A qualified end user is either a consumer or a restaurant/retail food establishment in the same state/Indian
reservation or within 275 miles of where the produce was grown. This requirement must also be met historically for the previous three years of the farm’s operations.

A farm with a qualified exemption (i.e. Tester Hagan Amendment) must still meet certain modified requirements (see citation 80 FR 74353).

Examples
Are You Covered Or Not?

1. Farm A makes annual sales of $245,000 in food grain sales and $250,000 in a same-state Community Supported Agriculture program featuring leafy greens.

Answer: Farm A falls under the Tester Hagan Amendment as a qualified exempt farm. This is because the annual food sales are less than $500,000 AND more than 50.1% of those sales go to a qualified end user (via the CSA).

2. Farm B makes $18,000 of apple and peach sales annually to a food hub.

Answer: Farm B is not covered because their total produce sales are less than $25,000.

3. Farm C makes $400,000 of apple and peach sales annually to a food hub.

Answer: Farm C is covered because their total produce sales are over $25,000.

4. Farm D makes $1,000,000 in annual sales of tomatoes for paste.

Answer: Farm D is not covered because the tomatoes are sold to a processor.

5. Farm E makes $200,000 in annual sales of wholesale tomatoes, $200,000 in annual sales of green beans to local restaurants, $75,000 in annual sales of peppers to a local farmers’ market, and $10,000 of annual sales in cheese to a local farmers’ market.

Answer: Farm E falls under the Tester Hagan Amendment as a qualified exempt farm. This is because the annual food sales are less than $500,000 AND more than 50.1% of those sales go to a qualified end user (via the local restaurants and farmers’ market).

References

Food Safety Modernization Act - Produce Safety
Rule: Agricultural Water

Overview:
The Produce Safety Rule (PSR) is one of the seven food safety regulations that are part of the Food Safety Modernization Act (FSMA). As of November 27, 2015 the PSR has been published in the Federal Register (citation 80 FR 74353). The PSR sets a series of science-based standards for the safe growing, harvesting, packing, and holding of produce grown for human consumption. Similar to other FSMA rules, the PSR aims to be proactive rather than reactive by focusing on high risk practices and identification of hazards within individual operations. The PSR sets standards for: agricultural water; biological soil amendments; sprouts; domesticated and wild animals; worker training, health and hygiene; equipment, tools, and buildings. Here, we describe the PSR standards for agricultural water.

Pre-Harvest Water Quality
Agricultural water that is applied directly to produce during the pre-harvest period must meet two sets of specific microbial standards. Both standards are based on levels of generic *Escherichia coli* in a 100 milliliter sample from the water source. Generic *E. coli* is used as a sign of fecal contamination (high numbers may indicate high levels of contamination). The levels of generic *E. coli* are evaluated based on the geometric mean (GM) and statistical threshold value (STV) of each water sample. The GM and STV must be less than or equal to 126 CFU *E. coli* and 410 CFU *E. coli* per 100 ml of water sample, respectively.

Definitions
GM: the Geometric Mean is the central tendency of the water quality, so it represents the average amount of *E. coli* in the source of water.

STV: Statistical Threshold Value represents the point at which 90 percent of the samples are below the value. It essentially the variability of the samples.

CFU: is a Colony Forming Unit; it represents the number of *E. coli* in the sample

MPN: is Most Probable Number, which is another unit used to estimate the number of *E. coli* in the sample

Tools are being developed to aid growers in calculating these values. Water that is used to irrigate sprouts does not fall under this rule. It must contain zero generic *E. coli* (see Sprout Safety Alliance via www.fda.gov).
Pre-Harvest Testing
1. Untreated Surface Water:
   Establishment of a microbial water quality profile (WQP) for each untreated agricultural surface water source that is applied directly to produce is required under the PSR.

   To establish the initial WQP:
   • 20 samples must be taken over a period of 2-4 years during the growing seasons.
   • The GM and STV for generic E. coli are calculated from these samples.

   After initial WQP is established:
   • Five samples must then be taken annually and combined with the most recent 15 samples to calculate a new GM and STV to confirm that the water is still meeting the standards (rolling WQP).

2. Untreated Ground Water:
   A WQP must also be established for each untreated agricultural ground water source that is applied directly to produce.

   To establish the WQP:
   • Four water samples must be taken during one growing season.
   • The GM and STV for generic E. coli are calculated from these samples.

   After initial WQP is established:
   • One sample must be taken annually and combined with the three most recent samples to calculate the new GM and STV (rolling WQP).

3. Treated Water:
   If water is treated before application, a WQP does not need to be established. Any treatment used must be a validated process to ensure that it kills enough bacteria. Also, this water must be monitored to ensure the treatment is working.

   If water from a public water system is used, obtain a certificate to verify treatment is complaint with the PSR.

Corrective Actions
   If pre-harvest agricultural water does not meet the PSR standards, several corrective actions can be taken to prevent discontinuing the use of the water source. These actions include:
   • Having a time interval between the last irrigation and harvest to allow for reduction of E. coli (the PSR allows for a specific reduction of E. coli per day up to four days; contact your local extension agent or specialist for more information).
   • Having a time interval between harvest and end of storage to allow for reduction of E. coli.
   • Treating the produce after harvest (e.g. washing).

Post-Harvest Water Quality
   The PSR requires water used in post-harvest production of produce to contain no detectable generic E. coli because it is likely that potentially dangerous microbes may be transferred to produce through direct or indirect contact.
Examples of water that must contain zero generic *E. coli* include:
- Water used for washing hands during and after harvest
- Water used on food-contact surfaces
- Water used to directly contact produce during or after harvest (includes water used to make ice)

If generic *E. coli* is detected, use of the water source will be immediately discontinued and follow-up actions will be taken to meet the standards.

**Post-Harvest Testing**

1. **Untreated Surface Water** can NOT be used for post-harvest produce
2. **Untreated Ground Water**:
   - Four water samples must be taken during one growing season.
   - All samples must have no detectable generic *E. coli*
   - After initial four samples:
     - One sample must be taken annually to confirm no contamination has occurred

**Public Water Systems**

There is no requirement to test water that originates from a public water system. The public water system is already presumed to be meeting the requirements set forth by law and is therefore in compliance with the PSR regulation.

**Recordkeeping**

Growers will be required to keep records for each of their water sources used for pre- and post-harvest applications. Examples of some documents growers may be required to maintain include:
- Documentation of inspection of any agricultural water system under the control of the farm
- Information or data supporting the efficacy of the chosen water treatment methods
- All sampling dates and water testing results
- Documentation from public water systems (if used)

**References**


Food Safety Modernization Act - Produce Safety Rule: Domesticated and Wildlife

Theresa Long1, Rachel Pfriem2, Laura Straw1

1Graduate student, Agriculture and Life Sciences, 2Research Specialist, Food Science & Technology, 1Extension Specialist, Food Science & Technology

Overview:
The Produce Safety rule (PSR) is one of the seven food safety regulations that are part of the Food Safety Modernization Act (FSMA). As of November 27, 2015 the PSR has been published in the Federal Register (citation 80 FR 74353). The PSR sets a series of science-based standards for the safe growing, harvesting, packing, and holding of produce grown for human consumption. Similar to other FSMA rules, the PSR aims to be proactive rather than reactive by focusing on high risk practices and identification of hazards within individual operations. The PSR sets standards for: agricultural water; biological soil amendments; sprouts; domesticated and wild animals; worker training, health and hygiene; and equipment, tools, and buildings. Here, we describe the PSR standards for domesticated and wild animals.

Domesticated and Wild Animals
Animals, both domestic and wild, may carry bacteria, viruses, or parasites that can make people sick. These animals may be:

- Domesticated animals – livestock, working animals, pets
- Domesticated animals from a nearby farm
- Wild animals – deer, raccoons, boar, birds

The FSMA PSR has established regulations for dealing with domestic and wild animals in produce growing and handling areas. The FSMA PSR standards for domesticated and wild animals apply only when there is a reasonable probability of produce becoming contaminated, i.e. when activities take place in an outdoor area or a partially enclosed building. The FSMA PSR directs growers to make all possible effort to avoid harvesting contaminated produce. The standards do not apply to fish used in aquaculture operations and when activities take place in a fully-enclosed building.

Listed below are the specific requirements.

Requirements
1. Visually examine on-farm sites for evidence of contamination during the growing season (e.g. feces):
   a. If evidence of potential contamination is found, grower should take measures to avoid the affected area, including placing flags around area

2. If grazing or working animals are allowed into produce fields, growers should:
   a. Wait an appropriate length of time between grazing and harvest (the PSR does not specify this interval, only that the grower consider intervals based on commodities and practices)
   b. Minimize introduction of hazards from working animals onto produce
3. If wild animals go into produce fields, growers should document the entry and evaluate whether the produce is safe enough to be harvested.

4. The FSIR does NOT require or allow farms to harm or kill endangered species, destroy animal habitat and/or clearing farm borders from produce fields or drainage areas.

References


Food Safety Modernization Act - Produce Safety Rule: Worker Training, Health and Hygiene

Overview:
The Produce Safety rule (PSR) is one of the seven food safety regulations that are part of the Food Safety Modernization Act (FSMA). As of November 27, 2015 the PSR has been published in the Federal Register (citation 80 FR 74353). The PSR sets a series of science-based standards for the safe growing, harvesting, packing, and holding of produce grown for human consumption. Similar to other FSMA rules, the PSR aims to be proactive rather than reactive by focusing on high risk practices and identification of hazards within individual operations. The PSR sets standards for: agricultural water; biological soil amendments; sprouts; domesticated and wild animals; worker training, health and hygiene; and equipment, tools, and buildings. Here, we describe the PSR standards for worker training, health, and hygiene.

Worker Training Health & Hygiene
Since the PSR aims to be proactive, it emphasizes training and health and hygiene programs for workers. Contamination of produce may occur when bacteria, viruses or parasites are transferred from a person, animal, or food contact surface to the produce. The PSR sets standards for worker training, health and hygiene that require growers to protect their produce from contamination by workers and visitors. Ill people can contaminate produce or food contact surfaces, which may result in the spread of pathogens. Training is an effective way to communicate risk reduction strategies to workers. Listed below are the specific requirements, though we encourage farms wishing to be FSMA compliant to read the full regulation (80 FR 74353).

Requirements
Workers: this includes all personnel who handle produce and work around food contact surfaces.

A. Training
1. Supervisors/Designated Food Safety Leaders
   i. Must take a standardized food safety curriculum that meets requirements outlined in FSMA – PSR (e.g. the Produce Safety Alliance has developed such a course: www.producesafetyalliance.cornell.edu/training)

2. All workers must be trained on the food safety risks associated with handling produce. There are several resources available, including your local VCE agent or specialist, which can provide training materials.

B. Health & Hygiene
1. Sick workers should notify supervisors, and should be reassigned to activities that do not require them to handle produce or food contact surfaces.

2. Workers should maintain personal cleanliness and hygienic practices while on the farm. For example, workers should wash

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hands thoroughly: scrubbing with soap and warm water and then drying them well. Workers should wash their hands: before starting work; before putting on gloves; after using the toilet; upon return to the workstation; after any break or other absence from the workstation; as soon as practical after touching animals or any waste of animal origin, or any other time hands may become soiled. For other requirements for worker hygiene practices, see 80 FR 74353.

3. Smoking, chewing gum, other tobacco products, and eating will not be allowed during produce handling activities (drinking is allowed in designated on-farm areas).

4. Steps should be taken to minimize contact with animals during produce handling activities.

5. Visitors should be made aware of the policies and procedures in place that are there to protect the produce and food contact surfaces from contamination. Bathroom and hand washing facilities must be available for visitor use. Visitors should be monitored to ensure they comply, or else should not be allowed on the farm.

References
