e-GRO Edible Alert
Volume 2, Number 2 January 2017

by Beth Scheckelhoff
scheckelhoff.11@osu.edu

An Introduction to the Food Safety Modernization Act's Produce Safety Rule

This first article provides an overview of FDA's newly established federal regulations governing the growing, harvesting, packing and holding of fresh produce, including leafy greens, microgreens, sprouts and other hydroponically-grown crops.

If you are involved in the production of fresh produce, you have likely heard about FDA's Food Safety Modernization Act (FSMA). President Obama signed FSMA into law in 2011, granting FDA the authority over developing and enforcing preventive and risk-based standards for growing, harvesting, packing, processing, and distributing domestic and imported food for humans and animals. The Produce Safety Rule (PSR) is one of seven foundational rules enacted by FSMA and the one most directly affecting our industry. FSMA-PSR's primary focus is preventing biological safety hazards (i.e, microorganisms that cause human illness) in the growing, harvesting and post-harvest handling of fresh fruits and vegetables.

Much of the language and terminology presented here is taken directly from the FSMA-PSR as published in the Federal Register. The complete rule and guidance documents can be found on the FDA FSMA Website: http://www.fda.gov/Food/GuidanceRegulation/FSMA/.

e-GRO Edible Alert
www.e-gro.org

CONTRIBUTORS

Dr. Nora Catlin
Floriculture Specialist
Cornell Cooperative Extension - Suffolk County
nora.catlin@cornell.edu

Dr. Chris Currey
Assistant Professor of Floriculture
Iowa State University
ccurrey@iastate.edu

Dr. Ryan Dickson
Floriculture Extension & Research
University of New Hampshire
ryan.dickson@unh.edu

Thomas Ford
Commercial Horticulture Educator
Penn State Extension
tgf2@psu.edu

Dan Gilrein
Entomology Specialist
Cornell Cooperative Extension - Suffolk County
dog1@cornell.edu

Dr. Joyce Latimer
Floriculture Extension & Research
Virginia Tech
jlatime@vt.edu

Dr. Roberto Lopez
Floriculture Extension & Research
Michigan State University
rglopez@msu.edu

Dr. Neil Mattson
Greenhouse Research & Extension
Cornell University
neil.mattson@cornell.edu

Dr. Garrett Owen
Floriculture Outreach Specialist - Michigan State Univ.
wgowen@msu.edu

Dr. Rosa E. Raudales
Greenhouse Extension Specialist
University of Connecticut
rosa.raudales@uconn.edu

Dr. Beth Scheckelhoff
Ext. Educator – Greenhouse Systems
The Ohio State University
scheckelhoff.11@osu.edu

Lee Stivers
Extension Educator – Horticulture
Penn State Extension, Washington County
ljs32@psu.edu

Dr. Paul Thomas
Floriculture Extension & Research
University of Georgia
pathomas@uga.edu

Dr. Ariana Torres-Bravo
Horticulture/ Ag. Econ., Purdue University
torres2@purdue.edu

Dr. Brian Whipker
Floriculture Extension & Research - NC State Univ.
bwhipker@ncsu.edu

Heidi Wollaeger
Floriculture Outreach Specialist - Michigan State Univ.
wolleage@anr.msu.edu

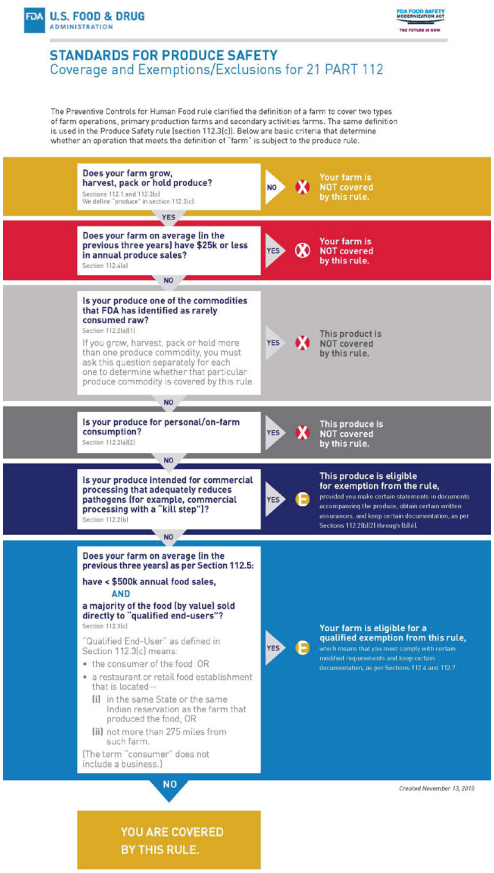
Must You Comply with FSMA-PSR?

The first question any producer must answer is whether they meet the regulation's definition of a "farm". The two lengthy definitions of a "farm" are intended to distinguish owner-operated production sites and off-site packing locations from commercial facilities. 1.) A ***Primary Production Farm*** (PPF) is a farm operating under one management in one general physical location (does not have to be contiguous) devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities. 2.) A ***Secondary Activities Farm*** (SAF) is an operation not located on the PPF that is devoted to harvesting, packing, and or holding raw agricultural commodities (i.e, produce in its raw or natural state), provided that the PPF that grows, harvests, or raises the majority of raw agricultural commodities harvested, packed, or held by the SAF owns, or jointly owns a majority interest in the SAF. If you do not meet the FDA's definition of a PPF or SAF, then you *are not covered* by the FSMA-PSR; however, you might be subject to one of the other six foundational rules, such as the FSMA-Preventive Controls Rule.

While all growers should be aware of the food safety risks on their farm, some may be excluded from the rule or eligible for an exemption. FDA has provided a flow diagram for determining whether produce from your farm is excluded from the rule, qualifies for an exemption, or is subject to the rule (right, http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472499.pdf).

Exclusions. The following are not subject to the PSR, including:

- Farms with ≤$25,000 in produce sales (on average for the last three years)
- Produce commodities that FDA has identified as rarely consumed raw: asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins;



winter squash; sweet potatoes; and water chestnuts

- Food grains, including barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g. cotton seed, flax seed, rapeseed, soybean, and sunflower seed)
- Produce grown for personal or on-farm consumption
- Produce that is not a raw agricultural commodity

Exemptions. If you are not excluded from the rule according to the above criteria, you may be eligible for a qualified exemption under the following circumstances, provided appropriate documentation and other conditions are met:

- The produce undergoes commercial processing to reduce the presence of microorganisms of public health significance (i.e., there is a “kill step”).
- If your farm has ***food sales*** (not just produce sales) averaging less than $500,000** per year during the previous

Cooperating Universities

UCONN

Cornell University

The University of Georgia

Iowa State University

Michigan State University

NC State

The Ohio State University

PennState Cooperative Extension College of Agricultural Sciences

Purdue University

University of New Hampshire Cooperative Extension

VirginiaTech Invent the Future

In cooperation with our local and state greenhouse organizations

Maumee Valley Growers — Choose the Very Best.

Connecticut Greenhouse Growers Association

Indiana Flower Growers Association

New Hampshire Plant Growers — Quality Garden Centers & Growers

Michigan Floriculture Growers Council

Virginia Flower Growers Association — Since 1954

lifga

NC Flower Power

three years; and the farm's sales to qualified end-users exceed sales to all others combined during the previous three years (i.e., more than 50%). 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, the same Indian reservation as the farm, or not more than 275 miles away.

- Proving eligibility for the qualified exemption requires three years of sales records to support the exemption. Business size determines compliance date as well as when you need to begin collecting sales records (Table 1).
- Farms receiving a qualified exemption must also prominently display their farm name and address on produce labels or at the point of purchase.

Key Requirements

Contamination of fresh produce from human pathogens generally occurs via these primary sources: humans, animals, water, soil, and/or the surfaces of equipment, tools and buildings. The FSMA-PSR addresses each of these sources and establishes science-based minimum standards for the industry to follow in the growing, harvesting, packing and holding of covered produce. Compliance dates for standards vary according to business size and for different parts of the rule (see Table 1 below). For example, standards specific to the sprout industry must be implemented earlier than other types of covered produce. Growers also have two additional years to comply with water regulations beyond their compliance date. Future e-Gro articles will discuss each of these routes of contamination in more detail.

In addition, the FSMA-PSR requires at least one supervisor or responsible party from each farm subject to the rule to complete food safety training from a FDA-approved standardized curriculum before their compliance date. Currently, the Produce Safety Alliance (PSA) (producesafetyalliance.cornell.edu) offers the only FDA-approved grower training course to satisfy this requirement. The PSA course educates growers on preventing biological safety hazards from contaminating produce on the farm by assessing produce safety risks, implementing produce safety practices (i.e., Good Agricultural Practices (GAPs)), monitoring practices, using corrective actions, and maintaining records. Growers interested in attending a PSA grower training workshop can find registered classes at the following link: https://producesafetyalliance.cornell.edu/training/grower-training-courses. Additional classes will be offered as more trainers become certified to teach the workshops.

Business Size	Annual average produce sales from three previous years	Compliance Dates				
		Sprouts	All Other Covered Produce	Water Quality	Qualified Exemption Labeling	Record Retention to Support Qualified Exemption
All other	>$500,000	01/26/17	01/26/18	01/26/20	01/01/20	01/26/16
Small	>$250,000-$500,000	01/26/18	01/26/19	01/26/21		01/26/17
Very Small	>$25,000-$250,000	01/26/19	01/26/20	01/26/22		01/26/18
Exempt	<$25,000	Not applicable				

Table 1. Compliance dates for all farms are tiered based upon business size.