

FDA Food Safety Modernization Act- key points for produce growers

Extension Food Safety Fact Sheet- December 21, 2015

The Food Safety Modernization Act (FSMA) was signed into law in January 2011 with the aim of preventing food borne illnesses, rather than only reacting to them. The first drafts of the proposed rules were released by the US Food and Drug Administration (FDA) in January 2013. FDA has incorporated thousands of comments received from various stakeholders into the produce safety final rule, which was released in November 2015. FDA continues to provide clarifications and more information on the rule, so additional information will be shared as it becomes available.

What is included in FSMA?

FSMA includes five main parts:

- 1) Produce Safety rule (final rule released November 13, 2015)
- 2) Preventative Controls for Human Food (final rule published September 10, 2015)
- 3) Preventative Controls for Animal Food (final rule published September 10, 2015)
- 4) Foreign Supplier Verification Program (dealing with imported food)
- 5) Accredited Third Party Certification (dealing with imported food)

What does the produce safety rule include?

The rule focuses on the growing, harvesting, packing and holding of produce and is very similar to the requirements of USDA Good Agricultural Practices (GAP) certification. This is the first time there have been federal governmental regulations in this area. Note that USDA GAP certification (or other food safety certifications such as Primus) are not required by governmental regulations, but may be required by a buyer.

Are there any exemptions of who will be covered by this rule?

Note that it is everyone's responsibility to sell safe, unadulterated food. However, the produce safety rule itself will not apply to the following:

- Growers selling \leq \$25,000/ year in produce sales (on average over previous 3 years)
- Those selling produce that is rarely consumed raw (such as potatoes). However, if the same grower also produces other products, those may be covered
- Produce used for personal/ on-farm consumption
- Produce intended for commercial processing with a "kill step" (i.e. tomatoes to be canned)
- Growers who on average over the past 3 years meet the following only need to meet certain modified requirements*:
 - o < \$500,000 annual food sales AND
 - o A majority of food (by value) is sold directly to a "qualified end user"
 - o A "qualified end user" is either:
 - § The consumer of the food 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 the farm

*The modified requirements include disclosing the name and address of the farm and maintaining certain recordkeeping requirements.

All other produce growers will be covered by the rule. In addition, if there is a food borne disease outbreak associated with your farm, you will no longer be exempt from the rule.

NOTE: Farms holding or packing raw produce from another farm will be covered by the produce safety rule and NOT the preventative controls rule (revised from first draft of the proposed rule).

NOTE: Any processing of produce beyond washing and normal harvesting (such as chopping, peeling, or roasting) would be covered by the Preventative Controls rule.

What are the main differences between FSMA and GAPs? (please note that this is our current understanding of the situation and that more details will be included in future clarifications from FDA)

- EVERY producer that is covered by FSMA will need to attend a certified 1 day FSMA training
 - o Regardless if you have GAP or other certifications, have been to other trainings, etc.
 - o MU and KSU Extension plan to start offering these courses in 2016/2017
- FSMA does NOT require a full on-farm food safety plan or an audit/inspection; rather those covered by FSMA will need to follow the food safety practices and testing required by FSMA. More information on exact methods of enforcement of FSMA will be forthcoming in the future.
- We understand that GAPs will be updated to basically match FSMA requirements; therefore, if you pass a GAPs audit, you should also be compliant with FSMA (but you still need FSMA training)
- FSMA requires no detectable generic *E. coli* in water that will directly contact produce after harvest, for handwashing, and when growing sprouts; water applied to growing produce must have a geometric mean of <126 CFU generic *E. coli*/ 100 mL water.

If I am covered, when do I need to comply?

Size of grower	Compliance with main rule	Compliance with water standards
Large growers (>\$500,000 annual produce sales)	November 2017	November 2019
Small growers (\$250,000- \$500,000 annual sales)	November 2018	November 2020
Very small growers (\$25,000- \$250,000 annual sales):	November 2019	November 2021

References/ resources available:

-FDA'S FSMA Website: www.fda.gov/Food/FoodSafety/FSMA/default.htm

-Cornell Produce Safety Alliance: <http://producesafetyalliance.cornell.edu/>

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