

Food Safety Modernization Act (FSMA)

Oregon Department of Agriculture
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FSMA: a short history

- Passed by US Congress in 2011
- Goal: greater focus on prevention
- Food & Drug Administration proposed rules in 2013
- Extensive comment and stakeholder involvement
- FDA has visited Oregon several times for input
- 7 rules finalized in 2015-2016

Final rules adopted

- Produce safety rule
- Human food preventive controls rule
- Animal food preventive controls rule
- Imported food rule
- Third party certification
- Sanitary transportation
- Intentional adulteration

At least 3 rules impact ODA programs

FSMA rule	Impacted program(s)
Produce Safety	<ul style="list-style-type: none">• Market Access & Certification (lead)• Food Safety
Preventive Controls (human food)	<ul style="list-style-type: none">• Food Safety (lead)• Market Access & Certification
Preventive Controls (animal food)	<ul style="list-style-type: none">• Animal Health

Implementation timeline

- Varies by rule
- Staggered compliance dates
 - Depend on business size
 - Delayed implementation dates for agricultural water portion of produce safety rule

Impacts to Oregon agriculture & food

- About 4,000 farms in Oregon grow fruits, nuts and vegetables
 - \$15,992 average estimated compliance cost
 - \$100 average cost for exempt farms
 - \$5,872 average cost for very small farms
 - \$38,741 average cost for very large farms
- 3,350 food and feed businesses will be affected
 - \$13,000 estimated average compliance cost
- Some businesses may be subject to multiple rules

Sources: National Ag Statistics Service, FDA economic impact analyses for produce safety and preventive controls rules

Produce Safety rule

- Several important exemptions
- Provisions related to
 - Agricultural water
 - Biological soil amendments of animal origin
 - Worker health and hygiene
 - Equipment, tools, buildings and sanitation
 - Domesticated and wild animals
 - Growing, harvesting, packing and holding activities
 - Sprouts requirements
- Training requirements

Preventive Controls rules

- Updates to basic sanitation requirements
- Hazard identification and mitigation process
- Exemptions for certain small businesses
- Significant recordkeeping
- New types of ag businesses affected
 - Produce packing houses
 - Mint stills
- Feed mills will also be affected

Implementation needed for success

- Outreach
- Training
- Onsite technical assistance
- Capital & operational improvements

ODA role – produce safety

- We have received a 5 year / \$3.5M FDA grant for:
 - Outreach
 - Technical assistance
 - Farm inventory (voluntary)
- Plan to hire 3 staff as part of this grant
- Plan to rely on OSU and other partners to provide classroom training
- Have not decided yet whether to apply for FDA funding for inspection and enforcement.

ODA role – preventive controls

- Human food:
 - Will likely adopt new rule by reference
 - May conduct FDA contract inspections to new rule
 - May conduct state inspections to new rule
 - Each inspection will take approximately 2X what it takes now
 - Beyond contract inspection \$, no federal funding currently available for increased state inspection time
- Animal food:
 - May adopt new rule by reference
 - May conduct animal food manufacturing inspections to FSMA requirements.

Conclusion

- New rules will have huge impact on nation's agriculture and food sector
- Agriculture and food sector needs assistance with implementation
- Still determining ODA role with respect to produce safety & animal food inspections
- SB 18 provides the framework for ODA to fully participate