

# Food Safety Modernization Act (FSMA)

Oregon Department of Agriculture  
April 20, 2017

# 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"><li>• Market Access &amp; Certification (lead)</li><li>• Food Safety</li></ul>
Preventive Controls (human food)	<ul style="list-style-type: none"><li>• Food Safety (lead)</li><li>• Market Access &amp; Certification</li></ul>
Preventive Controls (animal food)	<ul style="list-style-type: none"><li>• Animal Health</li></ul>

# 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 18A provides the framework for ODA to fully participate