



FSMA: Produce Safety Rule - Implementation

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Food Safety Modernization Act

- Signed into law January 2011
- 50 new rules, guidance documents, reports
- Cornerstone: Prevention





Prevention Standards

Sec. 105. Standards for Produce Safety

- Establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables
- Applies to raw agricultural commodities for which FDA determines that such standards minimize the risk of serious adverse health consequences or death.



FSMA Implementation

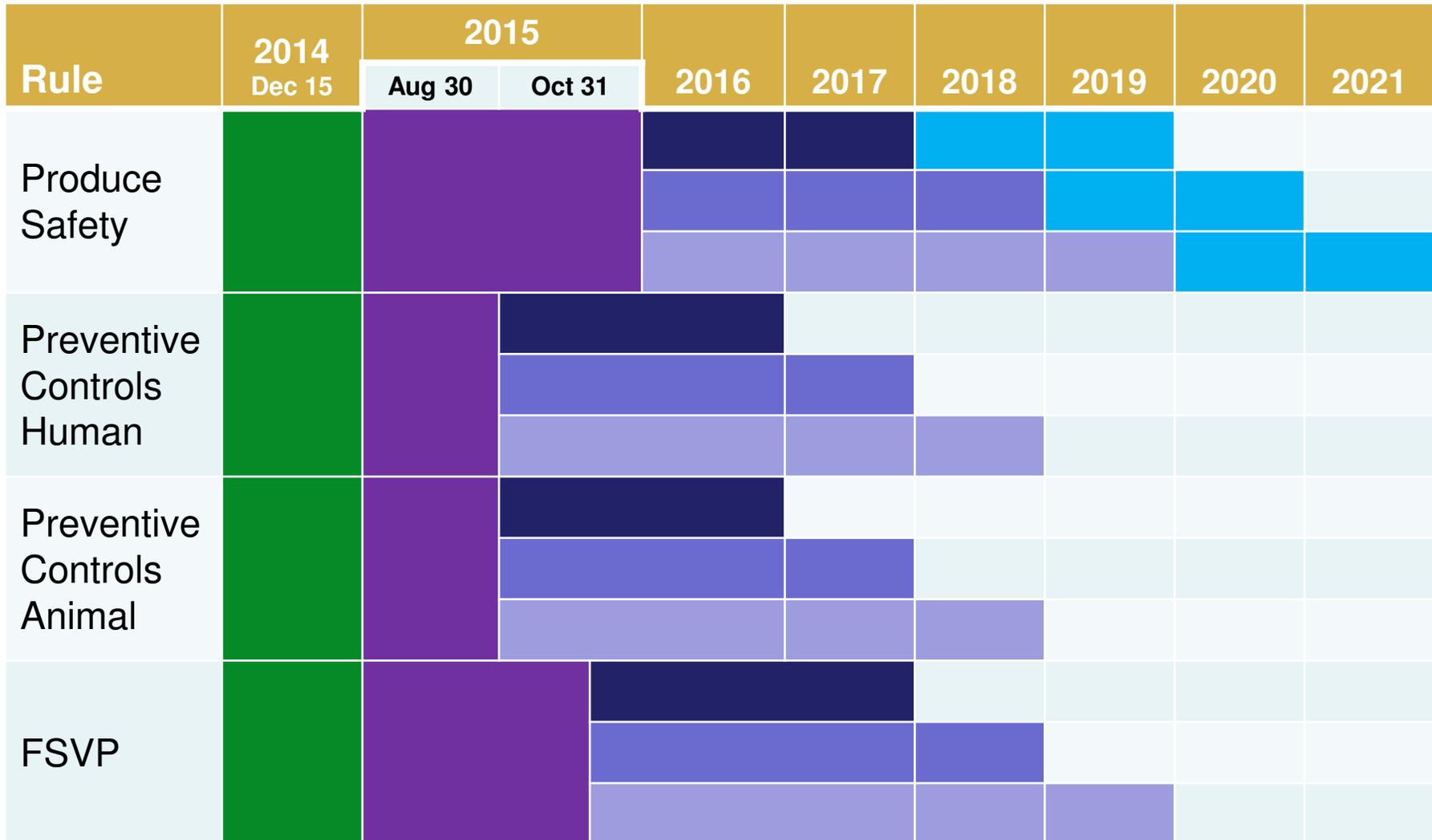
- Phase 1: Set standards
 - Develop regulations, guidance, policy
- Phase 2: Implement standards
 - Design strategies to implement standards
- Phase 3: Monitor, evaluate, refresh
- Stakeholder engagement throughout the process



Regulation	Proposal	Final (consent decree)
Preventive Controls (Human Food)*	Jan 16, 2013	Aug 30, 2015
Preventive Controls (Animal Food)*	Oct 29, 2013	Aug 30, 2015
Produce Safety*	Jan 16, 2013	Oct 31, 2015
Foreign Supplier Verification Program*	Jul 29, 2013	Oct 31, 2015
Third Party Accreditation	Jul 29, 2013	Oct 31, 2015
Sanitary Transport	Feb 5, 2014	Mar 31, 2016
Intentional Adulteration	Dec 24, 2013	May 31, 2016

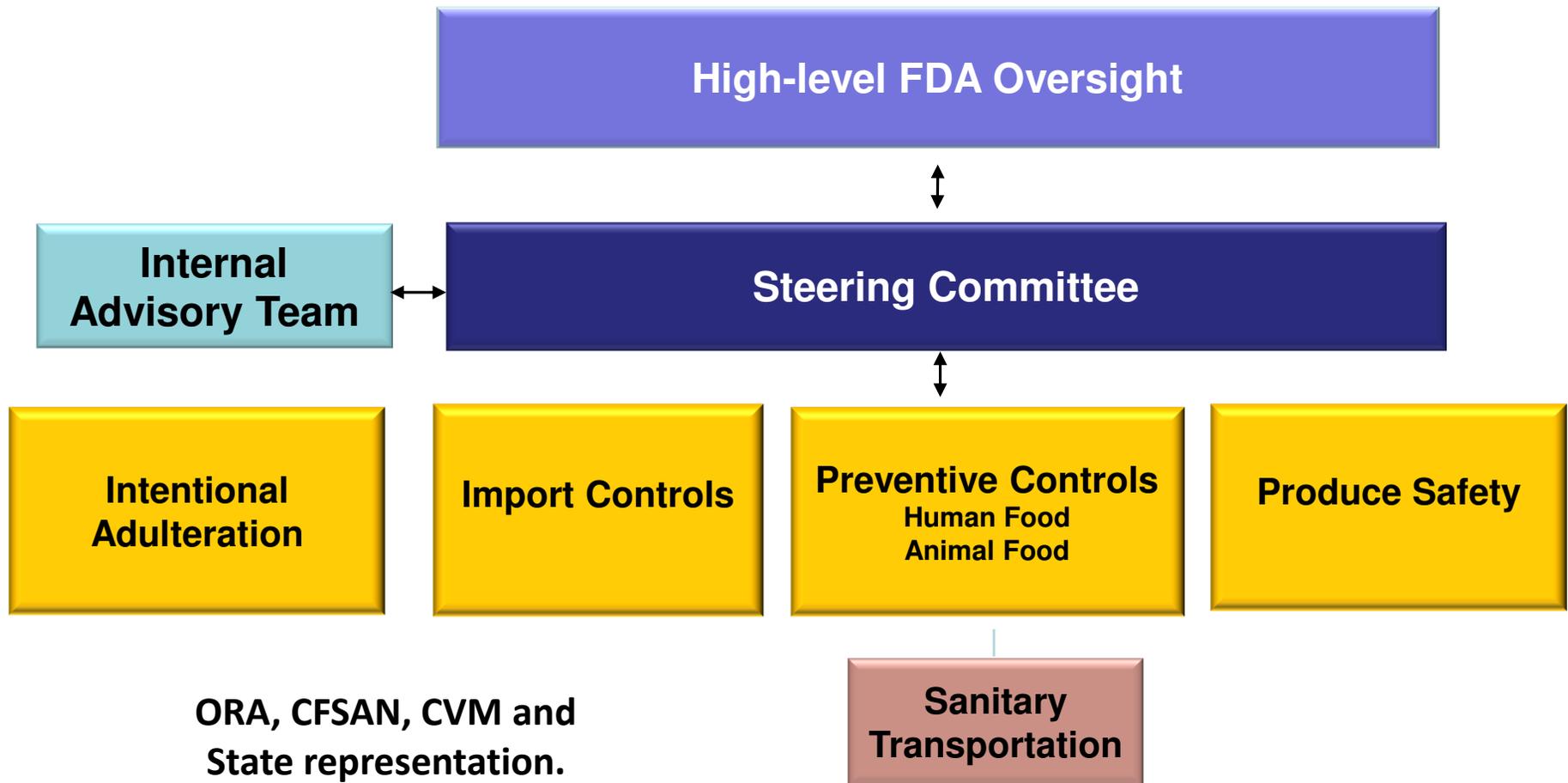
**Supplemental proposals published September 2014*

Compliance Dates by Business Size





Phase 2: Governance





FSMA Operational Strategy

- Provides a foundation for fully developing and implementing FSMA standards
- Captures in broad, high-level terms our current thinking on strategy and guiding principles



FSMA Operational Strategy: Produce Safety

- Broad, collaborative effort to foster awareness and compliance through guidance, education, and technical assistance



Key Principles

- Inspection, compliance functions specialized
- Invest in regulator training to promote consistent inspections, decision making
- Investigators and subject matter experts work together to drive compliance



Key Principles

- Robust data integration, analysis and information sharing
- Public health metrics
- Work closely with government counterparts and other food safety system stakeholders



Phase 2: Charge

- Develop a framework and multi-year implementation plan for ensuring compliance with regulations:
 - Inspections, compliance and enforcement
 - Data collection, analysis, updated IT
 - Performance goals and metrics
 - Training for regulators
 - Education, outreach and technical assistance for industry



Key Activities: Skilled Workforce

- Build a workforce with specialized skill set focused on produce.
 - Requires experienced regulatory personnel in field and HQ
 - Staffing dependent upon overall production, risk-based commodity/practice assessments
 - Work closely with regulatory partners (USDA, states) and other stakeholders (cooperative extension).



Key Activities: Skilled Workforce

- Build a workforce with specialized skill set focused on produce.
 - Comprehensive, Hands-On Regulator Training
 - Include PSA core curriculum training requirement
 - Regulator course with on-farm component
 - Continuing education



Key Activities: Relationship Building

- Develop working relationships with growers
 - Federal, state, academia, and farm partnerships
 - Conduct inspections with expanded emphasis on education and outreach
 - Pre-assessment program
 - Develop an incentive program for compliance



Stakeholder Engagement

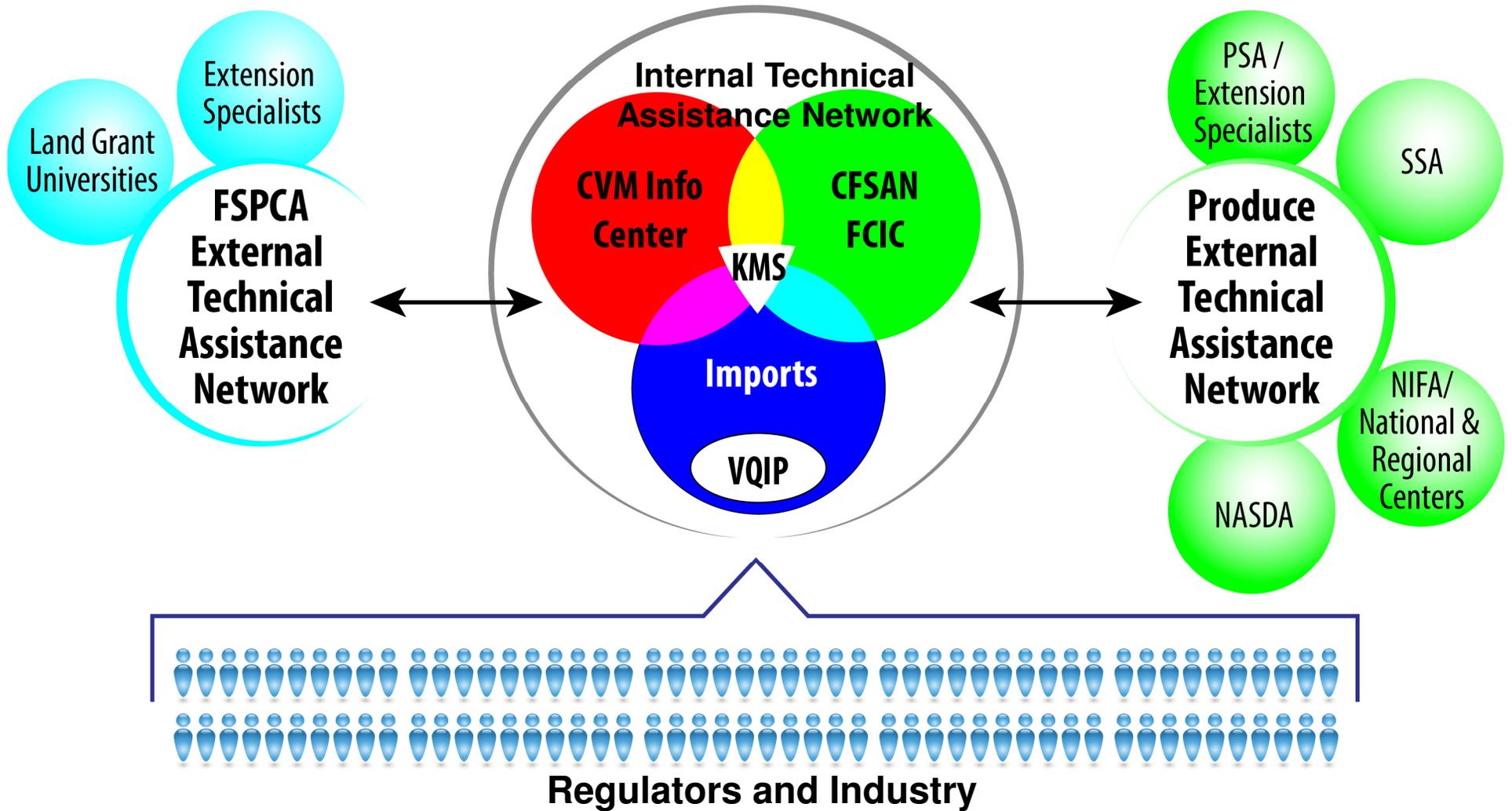
- Transparency Remains a Priority
- Next Phase: Inclusive/Coalition Approach
 - Engage stakeholders to help determine reasonable and practical ways to implement provisions and concepts before rules become final.
- Future: Partnerships/Collaboration Key
 - Establish mechanisms to foster industry understanding of standards and encourage firms to comply and initiate any corrections on their own.



Education, Outreach, and Technical Assistance

- Collaboration with industry, academia and researchers to provide training and educational materials to industry and regulatory officials
- Alliances
 - Produce Safety Alliance
 - Sprouts Safety Alliance
- FDA/NIFA grants

FDA Food / Feed Internal and External Tech Assistance Networks





Public Information Available

- Web site: <http://www.fda.gov/fsma>

The screenshot shows the FDA website interface. At the top, it displays the U.S. Department of Health & Human Services logo and the FDA logo with the text 'U.S. Food and Drug Administration Protecting and Promoting Your Health'. A navigation bar includes links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, and Cosmetics. The 'Food' section is active, showing a breadcrumb trail: Home > Food > Guidance & Regulation > Food Safety Modernization Act (FSMA). A sidebar menu under 'Guidance & Regulation' lists 'Food Safety Modernization Act (FSMA)' and 'The Law, Rules & Guidance'. The main content area features the title 'Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA)' with the subtitle 'Protecting Public Health by Strategic Implementation of Prevention-Oriented Food Safety Standards' and the date 'May 2, 2014'.



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Thank you