



FSMA Implementation

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Background

- Food Safety Modernization Act was passed in 2011 by President Obama
- FDA has proposed seven foundational rules to implement FSMA since January 2013
- Focus for today:
 - Preventive Controls for Animal Food Supplemental
 - Produce Safety Rule Supplemental
 - FSMA Implementation



Preventive Controls Rule for Food for Animals

**FDA FOOD SAFETY
MODERNIZATION ACT**



Comments and Outreach

- Comment period for original proposed rule closed March 31, 2014
 - Received over 2100 comments
 - We are still reviewing all comments
- 3 public meetings
- Numerous listening sessions with industry groups, including AFIA, NGFA, PFI, GMA, Brewers Assoc., UEP, NCC, NTF, United Fresh
- Letters from Congress, particularly related to coverage of breweries' spent grains

Issues Addressed in Supplemental

- Current cGMPs made more applicable to animal food
- Redefine very small business (less than \$2.5 million in sales)
- Withdrawal of qualified exemptions
- Proposed language for product testing, environmental monitoring and supplier controls
- Economically motivated adulteration
- Feed mills associated with farms



Produce Safety Rule



**FDA FOOD SAFETY
MODERNIZATION ACT**





Comments and Outreach

- FDA issued proposed rule on Jan. 16, 2013
 - Standards for growing, harvesting, packing, and holding of produce
- Stakeholder Input
 - 3 Public meetings; various outreach efforts
 - Comment period closed on Nov. 22, 2013
 - Over 15,000 comments received
- Limited re-opening of docket (prior to final)
 - Seek public comment on new/revised provisions

Issues Addressed in Supplemental

- Use of raw manure
- Agricultural water
 - Microbial quality standard for irrigation water and crop protection sprays
 - Frequency of testing
- Impact on wildlife and animal habitat
- Withdrawal of qualified exemption
- Farms excluded from coverage
- Packing or holding of own or others' RACs



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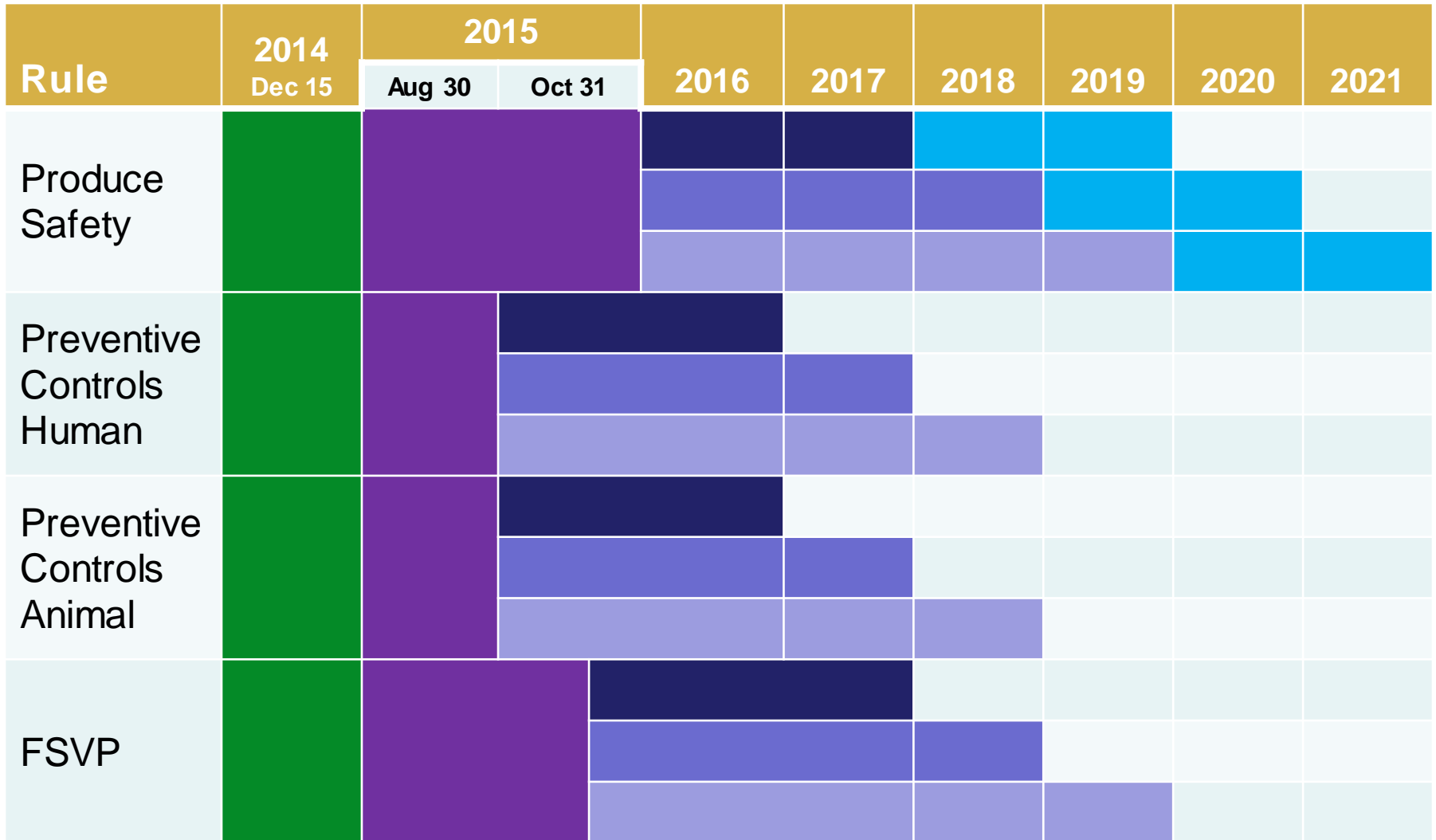




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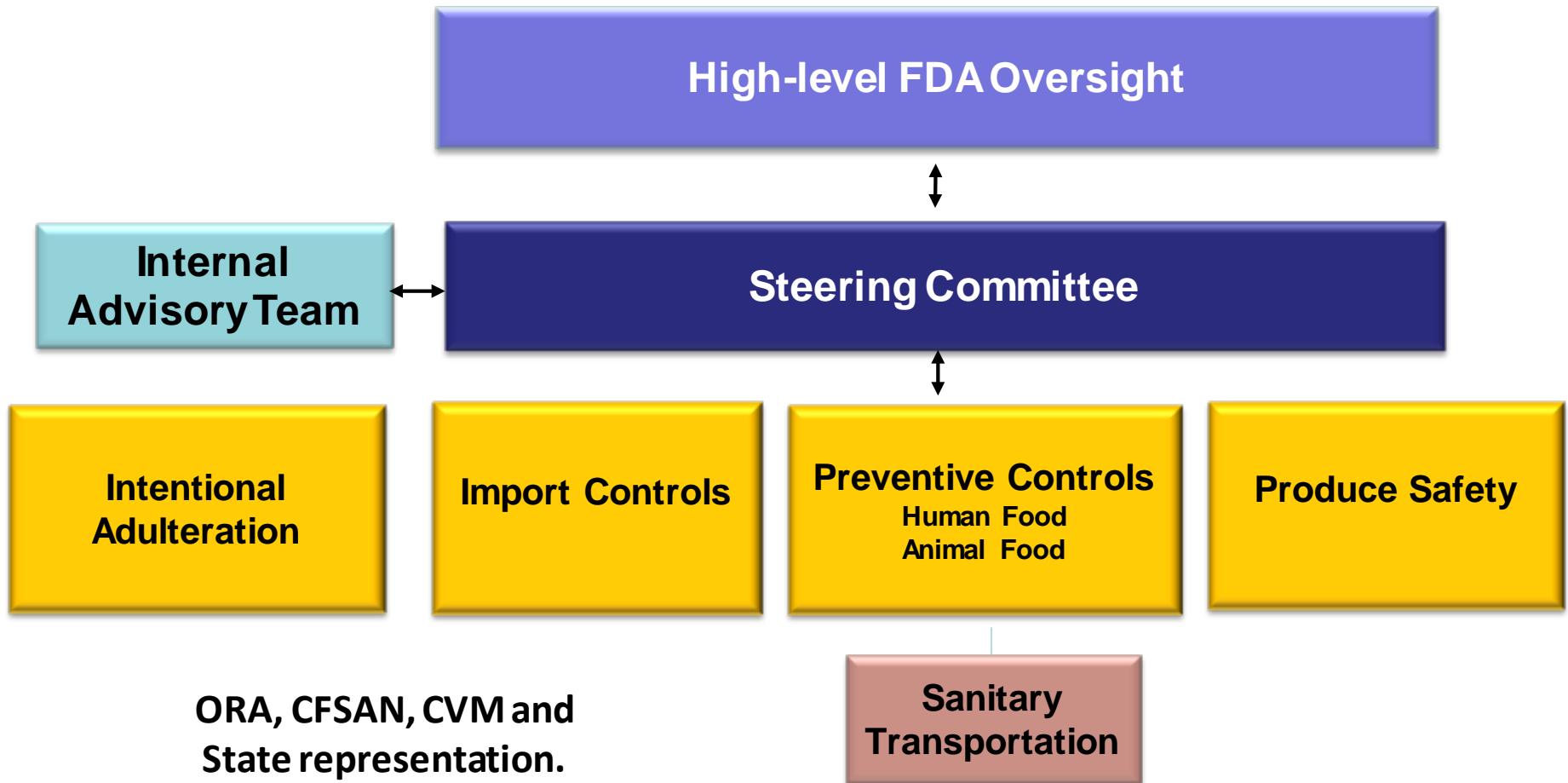
- Phase 1: Set standards
 - Develop regulations, guidance, policy
- Phase 2: Develop & Plan for gaining industry compliance with FSMA Rules
 - Design strategies and frameworks to implement standards
- Phase 3: Implement, monitor and evaluate

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

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm395105.htm>



FSMA Operational Strategy: Produce Safety

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



Key Principles

- Specialized inspection and compliance force
- Invest in regulator training to promote consistent inspections, decision making
- Investigators and subject matter experts work together to drive compliance



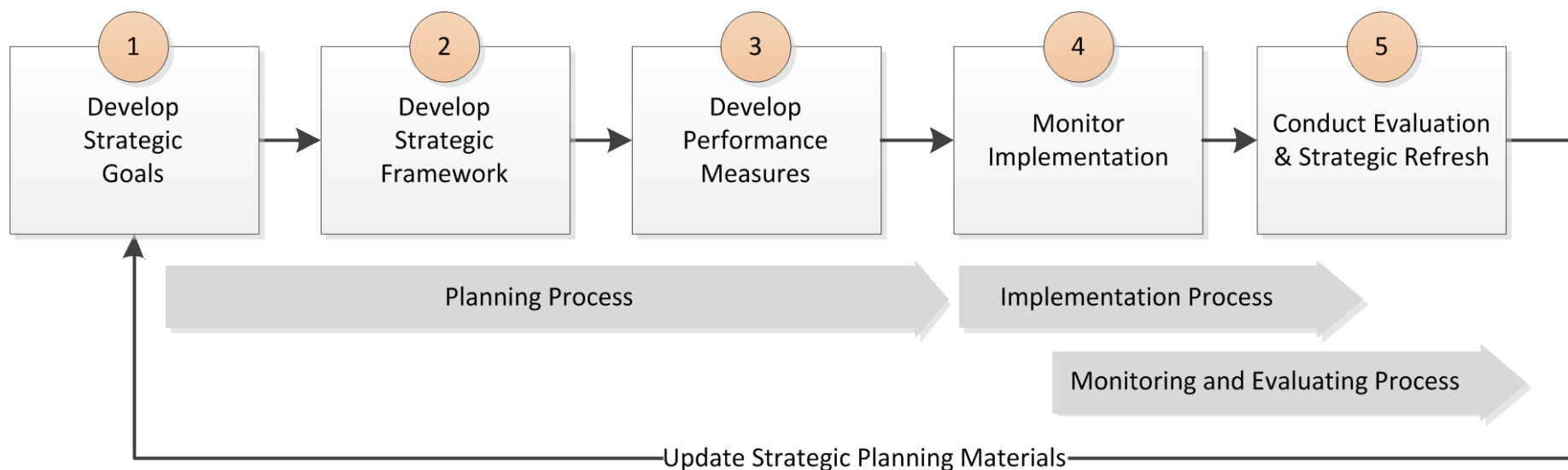
Key Principles

- 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

FDA Strategic Program Planning: 5 Steps



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
 - Farm protocol and etiquette
 - Continuing education

Key Activities:

Relationship Building

- Develop working relationships with farms
 - Federal, state, academia, and farm partnerships
 - Conduct inspections with expanded emphasis on education and outreach
 - Pre-assessment program
 - Develop an incentive program for compliance
 - Develop a program to evaluate application of the rule to identify inconsistencies



Stakeholder Engagement

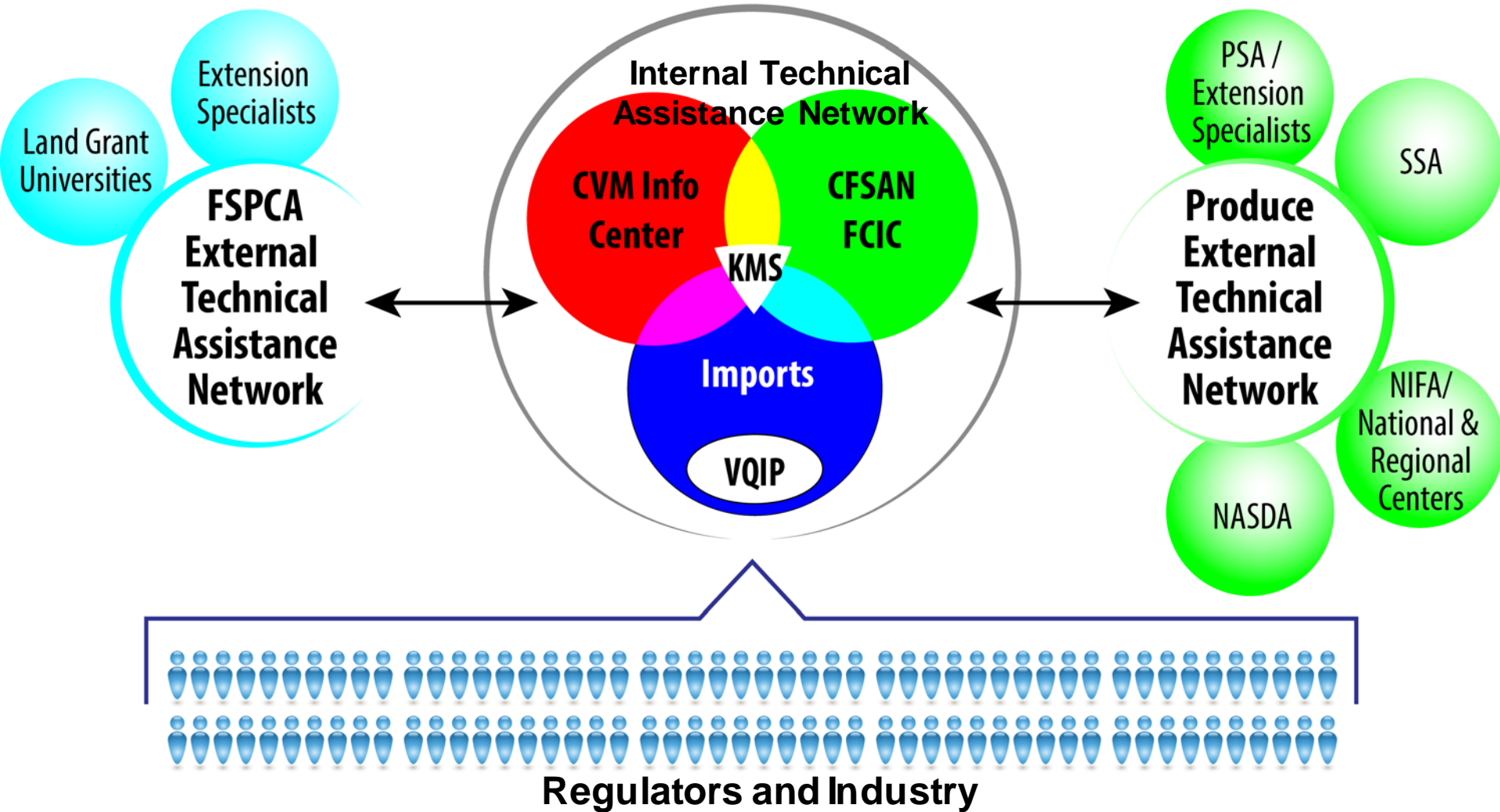
- Transparency Remains a Priority
- Next Phase: Inclusive/Coalition Approach
 - Engage stakeholders to help determine reasonable and practical ways to implement provisions and concepts before rules become final.
- Future: Partnerships/Collaboration Key
 - Establish mechanisms to foster industry understanding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



Education, Outreach, and Technical Assistance for Industry

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

FDA Food / Feed Internal and External Tech Assistance Networks



Public Meeting

- FDA Food Safety Modernization Act: Focus on Implementation Strategy for Prevention-Oriented Food Safety Standards.
- April 23, 2015, 8:30 a.m. to 5:30 p.m. and April 24, 2015, 8:30 a.m. to 12:30 p.m.
- Washington Marriott Hotel at Metro Center, 775 12th Street, NW, Washington, DC 20005.



Thank you