



FSMA: Produce Safety Rule - Implementation

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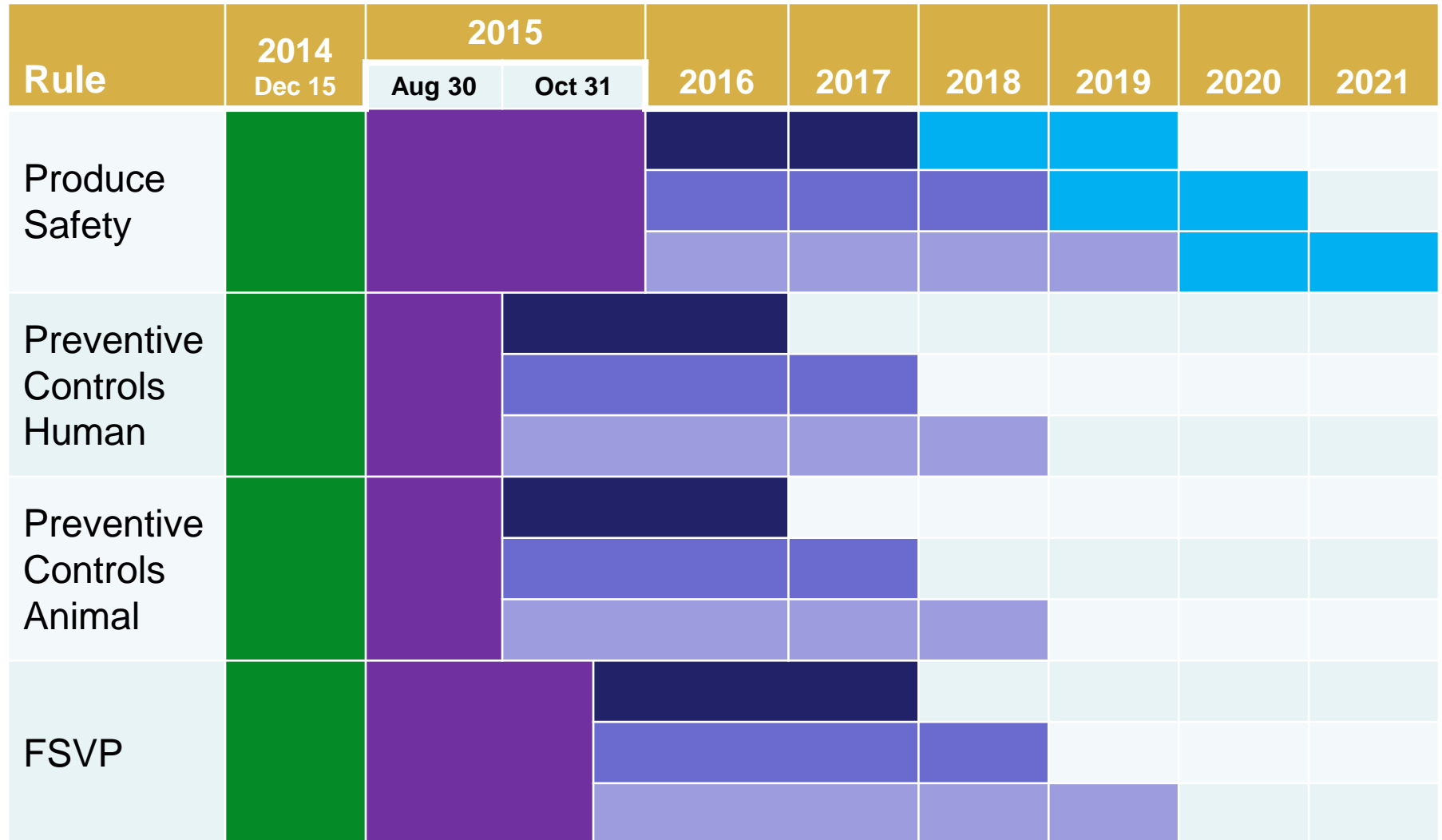
FDA/CFSAN and USDA/AMS

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FSMA Implementation

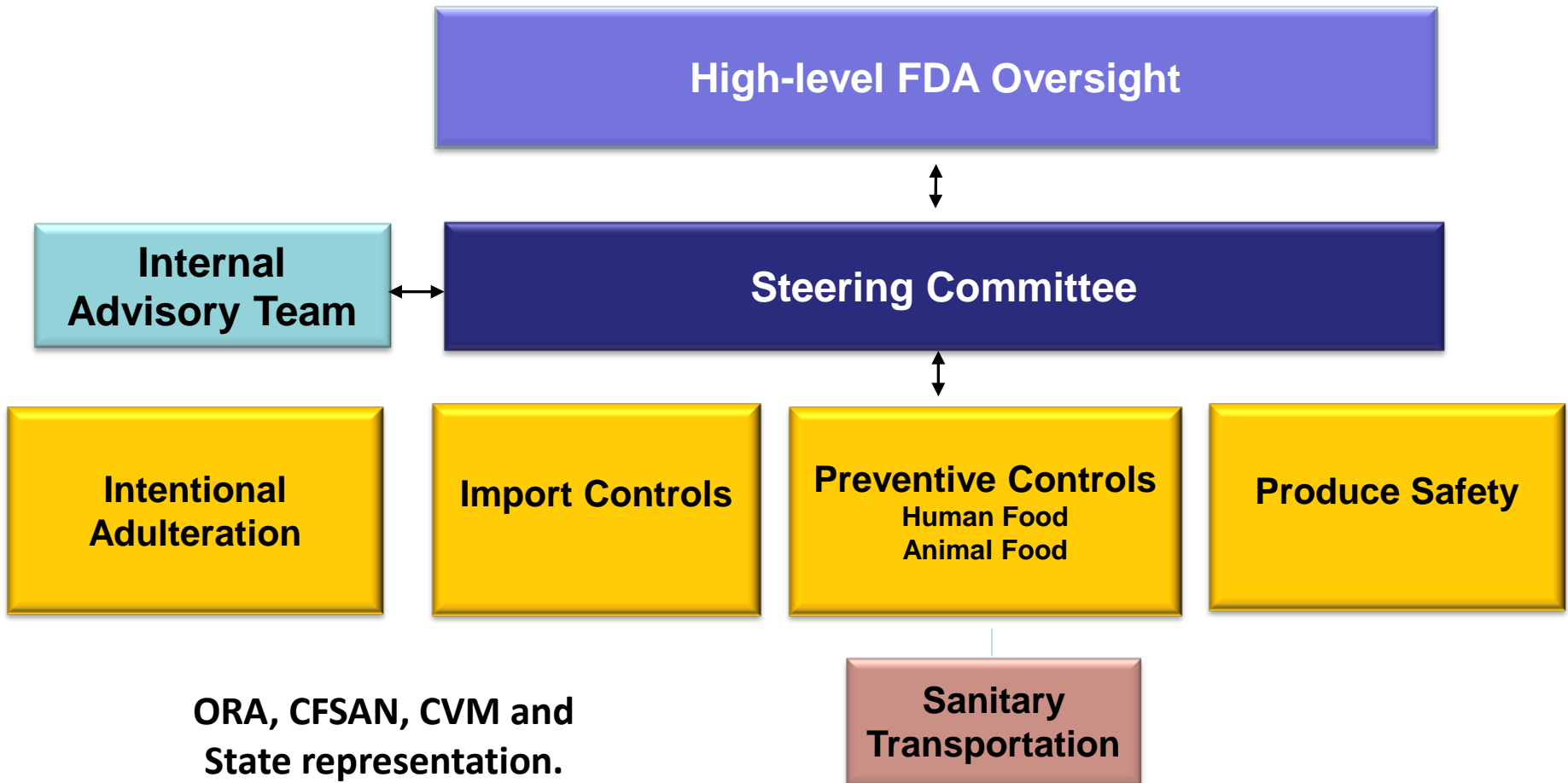
- **Phase 1: Set standards**
 - Develop regulations, guidance, policy
- **Phase 2: Implement standards**
 - Design strategies to implement standards
- **Phase 3: Monitor, evaluate, refresh**
- **Stakeholder engagement throughout the process**

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

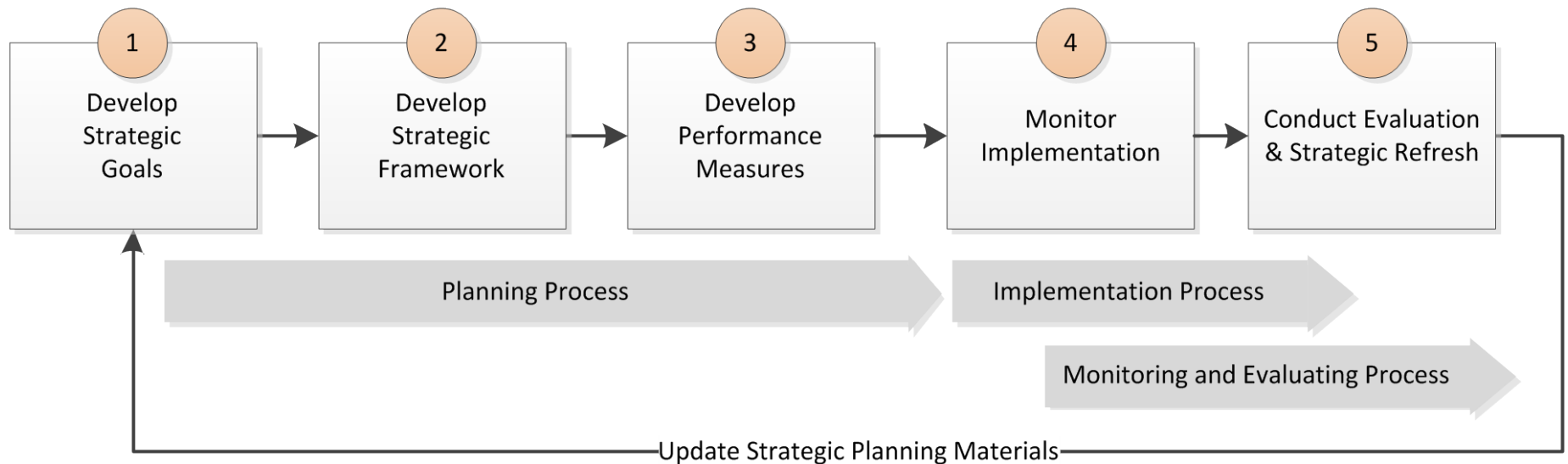
Key Principles

- 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

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



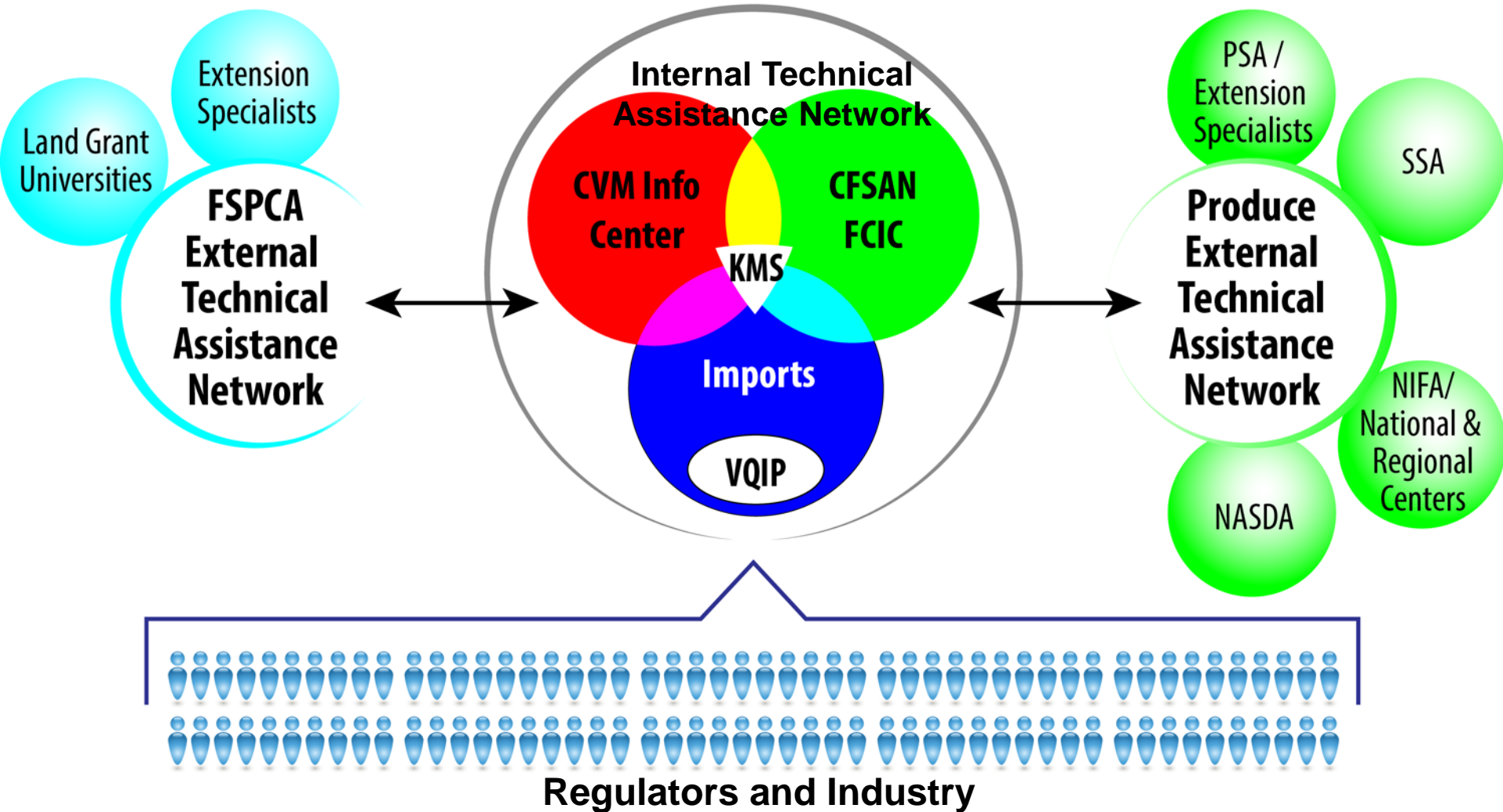
Stakeholder Engagement

- 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
- FDA/NIFA grants

FDA Food / Feed Internal and External Tech Assistance Networks





Joint GAPs Review Project

- USDA AMS, FDA CFSAN and ORA, and State partners
- Primary Goals
 - Review GAPs materials & make recommendations for revisions resulting in alignment with the FDA (final) Produce Safety Regulation
- Secondary Goals
 - Gain better understanding the public health implications of common farming activities and operations via the perspective of FDA personnel;
 - Gain a variety of farm-based experiences via USDA GAP audits;
 - Provide examples, scenarios, and materials to be incorporated into training programs for both agencies; and
 - Enhance the working relationships among both agencies and stakeholders



Thank you