FSMA 10 Years Later: Celebrating the Past and Looking Toward the Future

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FDA

FDA FOOD SAFETY
MODERNIZATION ACT

FSMA Implementation: *A Continuum*
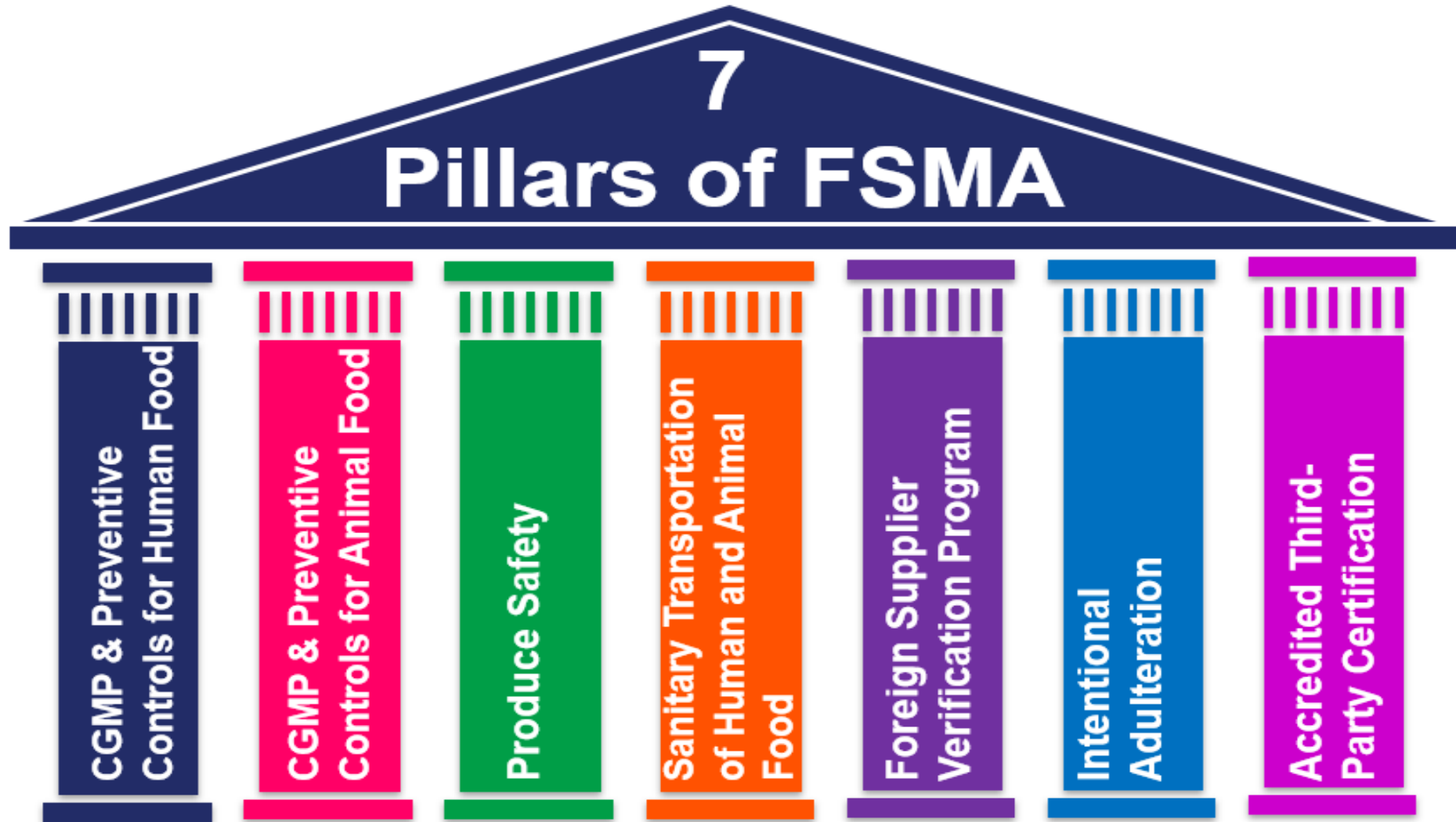
Phase 1
- Set Standards

Phase 2
- Design Strategies to Promote and Oversee Industry Compliance

Phase 3
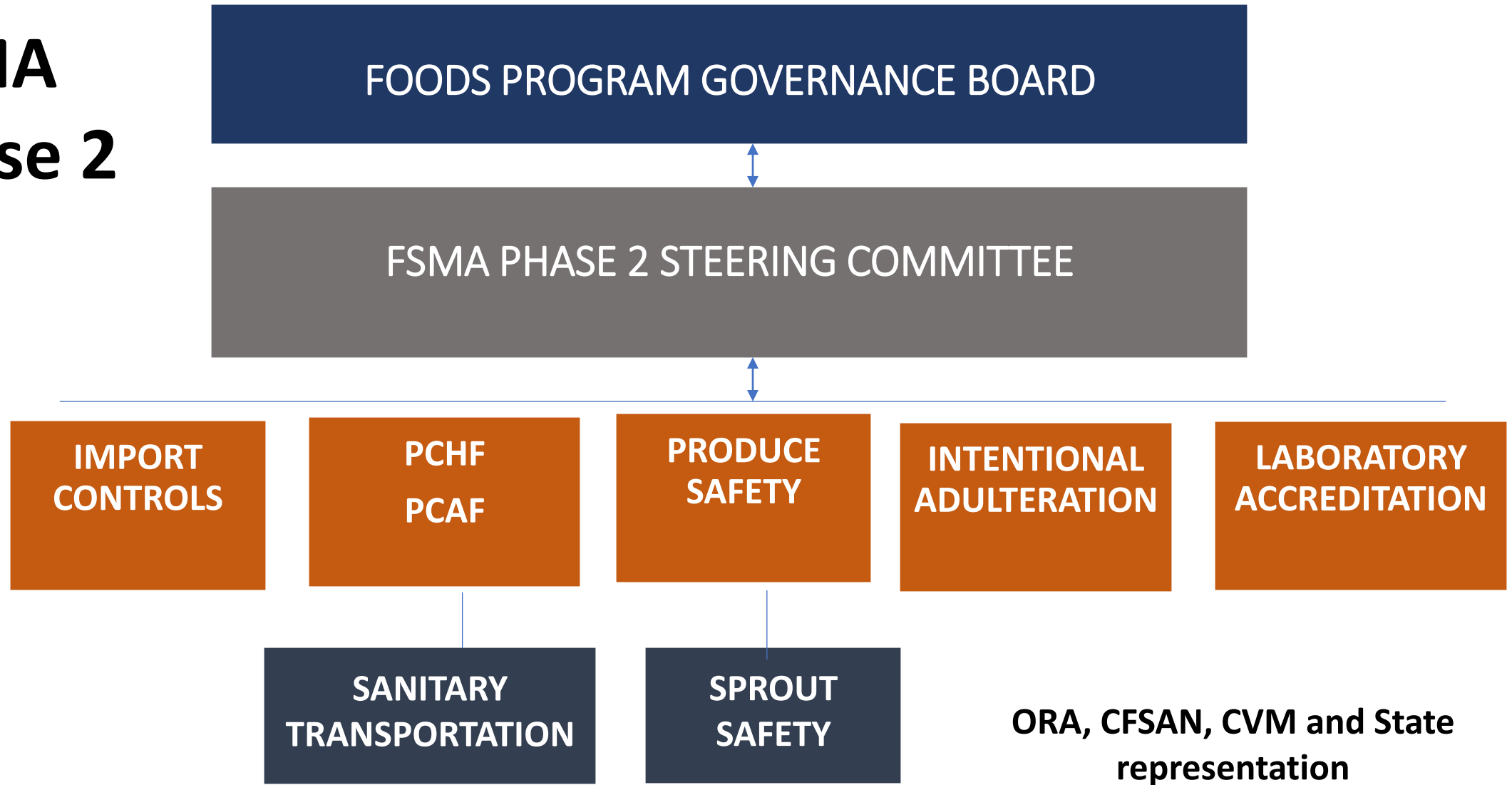Implement, Monitor, Evaluate, Refresh
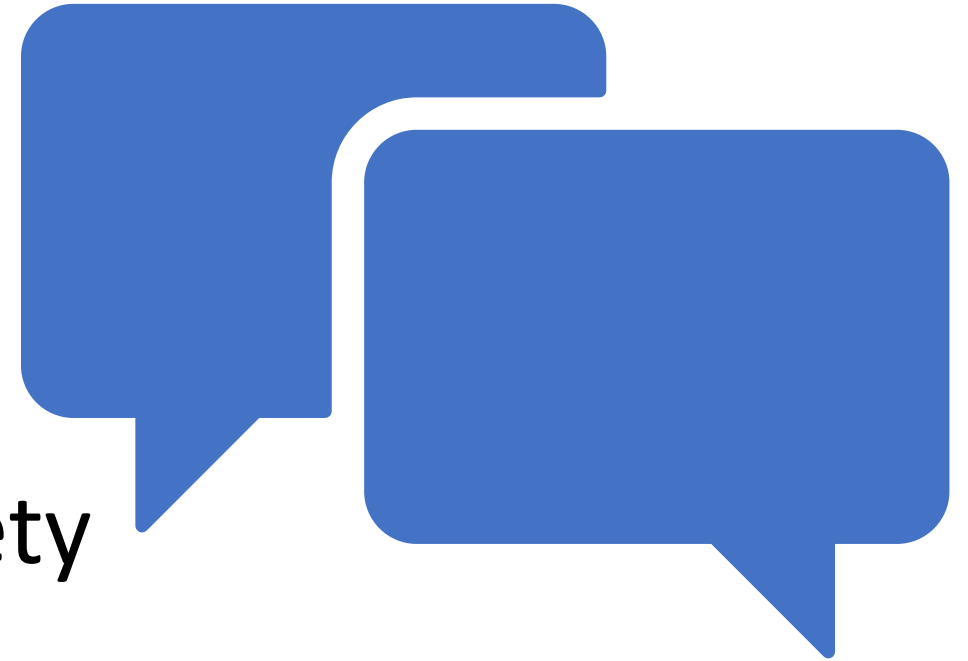
Food Safety Modernization Act (FSMA)

7 Pillars of FSMA

- CGMP & Preventive Controls for Human Food
- CGMP & Preventive Controls for Animal Food
- Produce Safety
- Sanitary Transportation of Human and Animal Food
- Foreign Supplier Verification Program
- Intentional Adulteration
- Accredited Third-Party Certification

FSMA Rules – Compliance Dates

Rule	Date Finalized	Compliance Dates
Preventive Controls for Human Food	Sept. 17, 2015	In effect for all covered businesses
Preventive Controls for Animal Food	Sept. 17, 2015	In effect for all covered businesses
Produce Safety	Nov. 27, 2015	Most provisions in effect for all covered farms; for agricultural water, compliance dates 2022-2024
Foreign Supplier Verification Programs	Nov. 27, 2015	In effect for all covered businesses
Accredited Third-Party Certification	Nov. 27, 2015	Participation is voluntary. Portal open for applications
Sanitary Transportation	April 6, 2016	In effect for all covered businesses
Intentional Adulteration	May 27, 2016	In effect for covered businesses

FSMA Chats and Readiness Events

- Initiated in 2013
- 50+ plus
- Topics: From FSVP to Food Safety Culture
- Web page:
  http://inside.fda.gov:9003/ora/fsma/ucm366919.htm

Planned Guidance/Resources

60+ draft and final guidance documents issued on topics such as:

- Hazards Guides
- Environmental Monitoring
- Validation of process controls

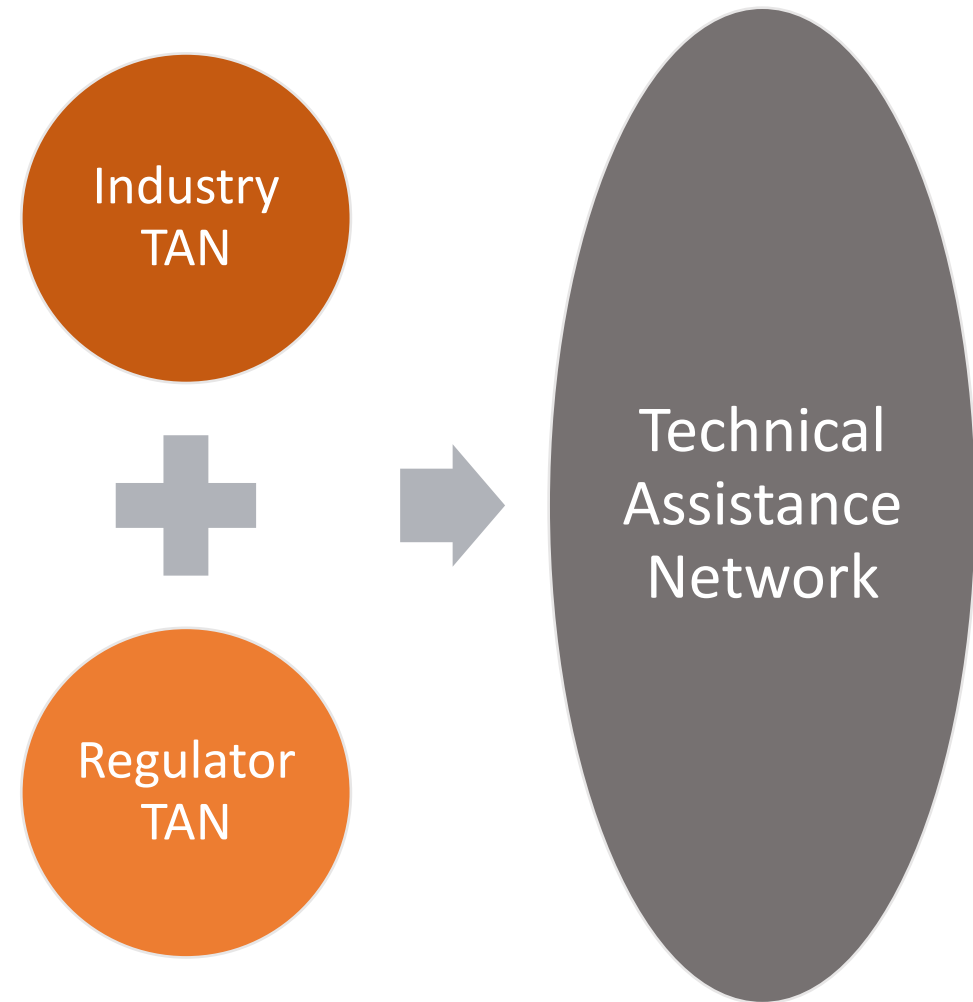**Fact sheets on commodity specific program areas such as:**

- FSVP
- Sanitary Transport
- PCHF and PCAF

Plan Builders

- Food Safety Plan Builder
- Intental Adulteraoin

Industry TAN

Regulator TAN

Technical Assistance Network

rTANworkgroup

FSMA Training - Industry

Produce Safety Alliance (PSA)

- Centered at Cornell University

Sprout Safety Alliance (SSA)

- Centered at the Illinois Institute of Technology

Food Safety Preventive Controls Alliance

- Centered at the Illinois Institute of Technology

FSMA Training – Regulators 2017-2022

FD254 PC for HF Regulators (30+)	VM102 CGMP AF Regulators (20+)	VM220 PC for AF Regulators (10+)	FD226 Produce Safety for Regulators (15+)
Participants FDA = 600+ State = 300+	**Participants** FDA = 300+ State = 300+	**Participants** FDA = 200+ State = 200+	**Participants** FDA = 80+ State = 300+

Dynamic Workforce

Development of IT Systems to Support FSMA

- Inspection Protocols and Tabular EIR
- Observation Corrective Action Report: OCAR
  - Corrective Action Report
  - Industry Portal
- Qualified Facility designation
- Third Party Program
- Voluntary Qualified Importer Program (VQIP)
- FSVP
- Laboratory Accreditation

Produce Safety Rule (PSR)

FDA continues to work with our state and association partners to implement the National Regulatory Program for produce safety inspections.
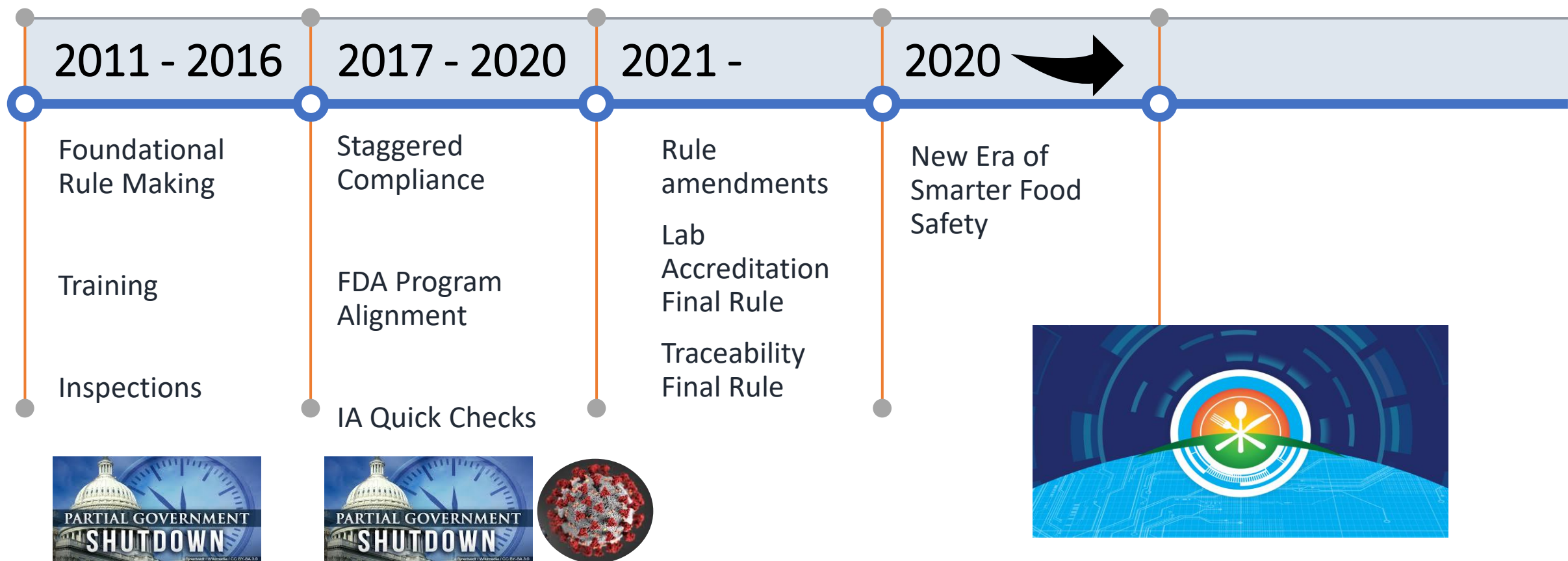
FDA is planning to publish its first produce farm Compliance Program later this year or early next year.

Ag Water

- FDA continues to work on rulemaking.

- One part of the rulemaking is updating the agricultural water provisions in the produce safety rule.

- FDA published a proposed rule to amend Subpart E in December 2021.

- In July 2022, FDA published a proposed rule to clarify the compliance dates for pre-harvest water and clarified the compliance dates for harvest and post – harvest water.

- FDA is also working on a proposed rule to amend the farm definition. Publication date- TBD.

New Era Core Elements

Invigorate Root Cause Analyses

Strengthen Predictive Analytics Capabilities

Domestic Mutual Reliance

Inspection, Training, and Compliance Tools

Outbreak Response

Recall Modernization

New Era of Smarter Food Safety Frequently Asked Questions | FDA

Collaboration

- State partners
- Alliances
- Associations
- Federal partners
- International partners

Questions?